02-13-09

3763

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of LENNART CARLSSON et al,	)	
	)	Group Art Unit: 3763
Appl. No.: 09/509,869	)	
Filed: June 15, 2000	)	
	)	Examiner: LUCCHESI

Title: ARRANGEMENT FOR OBTAINING RELIABLE ANCHORING OF A THREADED IMPLANT IN BONE

Approved.
JAB
3/17/09

PROTEST UNDER 37 C.F.R. 1.291

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to the provisions of 37 C.F.R. 1.291, the undersigned respectfully enters this Protest against the above-captioned pending patent application.

This Protest is timely filed under 1.291(a)(1), because it is being filed before a Notice of Allowance has been received, and before publication of the present application under 37 C.F.R. 1.211.

Pursuant to 37 C.F.R. 1.291(b) and 1.248(b), the undersigned hereby certifies that a copy of this Protest, including all of the supporting attachments, is being served upon the attorneys for the applicant, by today transmitting a copy of this Protest via first class mail addressed to the attorney for the applicant, Connolly Bove Lodge & Hutz, 1875 Eye Street. N.W., Suite 1100, Washington, D.C. 20006.

This is believed to be the first Protest submitted in this application. Nonetheless, pursuant to 37 C.F.R. 1.291(b)(2), the undersigned hereby certifies that this is the first Protest by the real party in interest who is submitting the Protest. The real party in interest is NEOSS, Inc.

A Statement Under 37 C.F.R. 1.291(c), including appended prior art, is provided herewith.

Dated: February 12, 2009

By: _____

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STATEMENT UNDER 37 C.F.R. 1.291(c)

SUBMITTED AS PART OF

PROTEST UNDER 37 C.F.R. 1.291

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INTRODUCTION

The pending claims are unpatentable for several reasons, and the Examiner should refuse allowance of the present application.

First, the claims are invalid under Section 112. The claims purport to recite a "tight threading." This term is hopelessly vague. "Tight" is a relative term, and the specification provides no guidance as to how to distinguish "tight" threading from threading that is not "tight." The claims also specify that the implant threading has a slight conicity that "extends along most ***or part*** of the length of the implant." Again, this is hopelessly vague, and this term does not appear to distinguish the claimed implant from the prior art. What does "part" of the length of the implant mean? For instance, would a slight conicity that extended along 0.001% of the length of the implant be sufficient to meet the claim (and if so, would the claim be operative under Sections 101 and 112)?

Second, the claims are unsupported by the specification and hence are invalid under Section 112, first paragraph. In discussing the conicity, the specification provides that this conicity extends along "at least *the greater part* of" the length of the implant. To the extent the claims can be understood, they appear to be directed towards an implant where the conicity can extend over the greater *or lesser* part of the length of the implant. Because the claims are unsupported by the specification as filed, they are not allowable and must be rejected.

All of the dependent claims are hence indefinite and invalid. Many of the dependent claims present independent and additional reasons for invalidity under Section 112. All of the pending dependent claims are based on claim 1. Some claims purport to specify the size of the implant relative to the bone of a patient. Claim 1, however, is an apparatus claim that is directed towards an implant itself. As such, the claim does not define a particular patient. Claims that purport to limit the size of the implant relative to use in a future patient are invalid under Section 112, second and fourth paragraphs.

Third, the claims are unpatentable over the prior art. All of the claims of the application are directed towards a threaded implant, such as an implant of the type commonly used in dental applications. The dental implant art is crowded, and the claims simply recite a combination of features common to many implants – features that have been known for years. Under *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. 398

(2007), the claimed combination of old features, all provided for known purposes, is not a patentable invention. At least some of the claims are anticipated by or obvious over the following references:

U.S. Patent 5,269,686, to James

U.S. Patent 5,902,109 to Reams

U.S. Patent 5,591,029 to Zuest

The claims likewise are unpatentable over any combination of the above and the references already of record, especially U.S. Patent 5,427,527 to Niznick et al. and U.S. Patent 5,527,183 to O'Brien.

II. BACKGROUND

The '869 application is the U.S. national stage of PCT application No. PCT/SE98/09182. The application claims priority to Swedish application number 97/04112-3, filed November 11, 1997. The PCT Application was published internationally on May 20, 1999 as WO99/23971 (but was not published under 37 C.F.R. 1.211, hence allowing for this Protest). The PTO's assignment records for this application are not available to the undersigned, but it is understood that the application has been assigned to Nobel Biocare.

The European counterpart of the present application issued, but faced third-party protests after issuance. Copies of these protests and the art cited therein are available on request from the undersigned; also, it is expected that the assignee will submit this information as part of its duty of candor and disclosure under Rule 56.

Reproduced below are the independent claims of the '869 application:

1. Threaded implant for obtaining reliable anchoring in bone substance, the bone substance being provided with a hole in whose side wall an internal threading may be established which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance, wherein the implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of the

length of the implant and which cooperates with a circular cylindrical hole in the bone substance to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole, the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals which provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking-up of the fine bone trabeculae which surround the hole in the bone, and wherein the front portion of the implant is designed with a conical thread which has a conicity exceeding the conicity of the slightly conical thread.

16. Threaded implant for obtaining reliable anchoring in bone substance, the bone substance being provided with a hole in whose side wall an internal threading may be established which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance, wherein the implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of the length of the implant and which cooperates with a circular cylindrical hole in the bone substance to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole, the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals which provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking-up of fine bone trabeculae which surround the hole in the bone, wherein four thread spirals are arranged together with four cutting edges.

III. THE CLAIMS ARE INVALID UNDER SECTION 112 BECAUSE THEY ARE UNCLEAR AND VAGUE, BECAUSE THEY ARE NOT SUPPORTED BY THE SPECIFICATION, AND BECAUSE THEY ARE IMPROPER DEPENDENT CLAIMS

A. The term "tight threading" is relative and undefined

Both of the independent claims of the application specify a "tight" threading. "Tight" is a relative term – "tight" is the opposite of "loose," and the assignee evidently envisions that an implant may have either tight threading or threading that is not tight. To determine whether a particular threaded implant is covered by claim 1 or claim 16, one is required to know whether the threading is "tight" as the claims require. The specification, however, does not provide any guidance for how one might determine "tightness."

As the Examiner is aware, Section 112 requires that a patent claim must "particularly pointing out and distinctly claim[]" the subject matter sought to be patented. When considering relative terms, the M.P.E.P. provides, at M.P.E.P. 2173.05(b), that the specification or the art must provide guidance as to the meaning of this term:

> When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention.

The specification is of greatest significance. Where the specification does not provide guidance as to the meaning of a relative term such as "tight," the claim is invalid and must be rejected under Section 112. In a similar case, *Ex parte Oetiker*, 23 U.S.P.Q.2d 1641 (Bd. Pat. App. & Inter. 1992), the claim at issue used the term "shallow." The claim was held to be indefinite and unpatentable, because the specification provided no guidance as to the meaning of this term:

> In the present case, there are no explicit guidelines in appellant's specification to enable one skilled in the art to distinguish the claimed structure from structures in which the depression means is not relatively shallow. Absent such guidelines, we are of the opinion that a skilled person would not be able to determine the metes and bounds of the claimed invention with the precision required by the second paragraph of § 112.

23 U.S.P.Q.2d at 1655.

Here, the specification contains only a few passages that relate to "tightness." At page 6, lines 28-34, the specification states that the implant should provide a "tight threading which permits effective integration with the bone substance" during osseointegration of the implant. At page 8, lines 10-21, the specification expands on the earlier passage at page 6, but says nothing further about how to determine whether threading is "tight." While the specification attempts to provide guidance as to other claim terms, such as "slight conicity,"[1] the specification provides no teachings at all as to the meaning of "tight" threading. All that the specification teaches is that the tightness of the threading permits "effective integration with the bone substance" during osseointegration.

The standard expressed in the specification – "effective integration" – is no standard at all. Many types of threading in the prior art allow for successful osseointegration, and therefore the specification does not assist one of skill in the art in understanding this term. In addition, and perhaps more significantly, there is no support for the claimed benefits of tight threading in relation to reliable anchoring and subsequent successful osseointegration. There is no clinical data, and there is no general consensus in the dental implant field, to support a claim that the implant threading shown in the specification is superior to other threading configurations. Much less is there any teaching as to how "tight" the threading must be to attain these purported benefits.

Nor is the meaning of "tight" threading apparent to one skilled in the art. As a preliminary matter, it is not clear what the "tightness" of the threading is to refer – is it the pitch of the threads, the distance between threads on a multi-threaded implant, or something else altogether? The art is replete with different types of threading on an implant. More generally, the mechanics of applying threading to screws and the like has been well understood for decades. There are many parameters associated with threads and the nomenclature of threading (pitch, thread angle, etc.) is well defined in the art. "Tightness" is not a known thread parameter per se, and this term evidently is used in the specification as a modifier. To which parameter does the applicant intend "tight" to refer? The specification does not say.

"Tightness" might be understood in other contexts to refer to the pitch of the threads, but that is evidently not the case here. The specification provides a range of

[1] This is discussed at page 11, lines 26-30 and the drawings, with reference to the angle of inclination α.

pitches for the threads on the implant,[2] but provides *separately* that the threading should be "tight." This signifies that "tightness" means something different. Similarly, "tightness" might be understood in other contexts to refer to the distance between successive threads, but that cannot be the meaning here. The specification provides that tightness relates to osseointegration, and there is nothing in the prior art to suggest that closely spaced plural threads have anything to do with the effectiveness of osseointegration. Thus, it is not clear what "tight" threading might mean.

Additionally, there is no known guidance in the art for demarcating "tight" threading from threading that is not tight. When does threading become "tight"? What is the dividing line between tight threading and threading that is not tight? Given a particular implant (and even knowing what parameter "tight" is supposed to modify), how would one determine whether threading is "tight" or not? There is no such thing as a standard for "tight" implant threading – this is the applicants' term, and the applicant has not defined it.

It is significant that the applicant has attempted to define another of the claim terms in the specification – "slight" conicity. "Slight" is also a relative term, and, as discussed above, the specification contains numerical parameters to guide the reader as to what this term means. Indeed, the applicant found it insufficient to define this term using the text of the application alone, but rather found it necessary to define the term with reference to the drawings. Yet for another relative term – "tight" – the specification provides no guidance.

If the applicant recognizes the term "slight" as a relative term that requires definition, how can the term "tight" be deemed adequately defined? By defining "slight," the applicant concedes that this is a term of relativity and that definition is required. "Tight" is likewise a relative term. By failing to define "tight," the applicant has presented an invalid claim set, if not an inoperative specification altogether.

Because the term "tight threading" is incomprehensible, the claims do not satisfy Section 112, and must be rejected on this basis.

B. The term "part of the implant" is vague

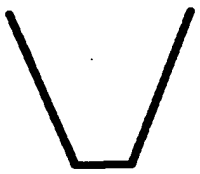
The claims specify an implant with slight conicity. This slight conicity "extends along most ***or part*** of the length of the implant." The meaning of this unclear. How much

[2] At page 7, the specification provides that the thread angle of inclination should be 0.5 - 2°.

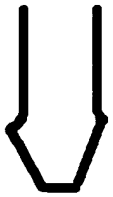
is "part" of the length of the implant? Is it necessary for the slight conicity to extend along 50% of the length of the implant? 5%? What about 0.005%? How does this feature add to the patentability of the claim, or differentiate the claim from prior implants? Manufacturing tolerances typically are in the range of +/- 0.05 mm on the diameter, or an angle of around 0.5 degrees depending on the length of the implant. These manufacturing tolerances necessarily would introduce slight conicity in many prior art implants. This feature is vague and unclear.

The specification provides no guidance in this respect. It does not directly indicate why slight conicity is desired for the implant threading. At one point (e.g. page 8. ll. 31-35), it is suggested that the slight conicity assists with counteracting tendencies for bone to break as the implant is inserted (this is allegedly "[b]ecause the pressure between the implant and the thread does not fall" with insertion). If this is the purpose of the slight conicity, what "part" or portion of the length of the implant must be slightly conical to achieve this result? Again, the specification is silent on this point, and nothing in the prior art provides any guidance either. There is no data in the specification to support the assertion that the "slight conicity" actually assists with counteracting tendencies for bone to break as the implant is inserted

The claim language itself, in its present form, suggests that the slight conicity "cooperates with a circular cylindrical hole" to cause "greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole, the degree of forcing out being adapted in relation to the softness of the bone substance." What does this mean? This lends even further vagueness to the claim. How does slight conicity itself cause greater forcing out of bone substance at the outer part of the hole? An implant having this general shape might satisfy that clause:



but not an implant having this general shape:



If the first implant depicted above is inserted into bone, the bone will be forced out to a greater extent towards the top of the hole. But that is not true for the second depicted implant – the bone will be forced out to its greatest extent by the slightly conical section and will be forced out more towards the *bottom* of the hole. The portion of the length of the implant would not appear to be relevant, but rather, what is relevant is the location of the conical portion relative to other portions of the implant.

Even further, the claim specifies that "the degree of forcing out being adapted in relation to the softness of the bone substance." What does this mean? The undersigned does not understand "adapted in relation to the bone softness." Is the applicant attempting to define the claimed subject matter with reference to unclaimed bone substance? Why would the softness of the patient's bone dictate how far the bone is moved aside to make room for the implant as the implant is inserted? The bone is forced aside to the extent necessary to accommodate the implant, irrespective of the hardness of the bone, because the implant material is not deformable in relation to bone. It is well known that there is a large difference between the E-modulus of bone and that of a metal implant. How would one skilled in the art understand what "part" of the implant must be slightly conical to achieve this result?

M.P.E.P. 2173.03 specifies that "[a]lthough the terms of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty." Here, the claims are inconsistent with the common knowledge in the art, and are invalid for this additional reason.

C. The term "part of the implant" is not supported by the specification

The specification provides, at page 7, lines 2-6, that there should be a "slight conical narrowing" that "extends along at least *the greater part* of the length of the implant." This is the only teaching in the specification as to the dimension of the "slight conicity." This teaching does not support the present claims, which purport to allow the conicity to extend along "most or part" (i.e., apparently any portion of) the length of the implant. M.P.E.P. 2163 *et seq.* is applicable here, and, as the Examiner is aware, these sections mandate that the specification must support the claimed invention. *See, e.g., Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, inter alia, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means.). M.P.E.P. 2163.05 and *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) are particularly relevant. The claims specify a range of the slight conicity (extending along "most or part" of the length of the implant), while the specification does not disclose this range. In *Purdue Pharma*, the court considered a similarly broadened range, and held "the specification does not clearly disclose to the skilled artisan that the inventors... considered the . . . ratio to be part of their invention . . . ." The claims are hence unsupported by the specification and are invalid for this reason.

To the extent that the extension of the slight conicity over the greater part of the length of the implant is deemed an essential feature of the claimed invention, M.P.E.P. 2172.01 precludes patentability. This section specifies that "a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention." The claims are thus invalid for this additional, independent reason.

D. Claims 6 and 13-15 are improper dependent claims and are vague

Claims 6 and 13-15 are as follows:

> 6. Implant according to claim 5, wherein the implant is arranged with a minimum diameter which corresponds to or is slightly greater than the diameter of the hole in the bone substance.

13. Implant according to claim 1, wherein the bone substance is a jaw-bone.

14. Implant according to claim 1, wherein the bone substance is soft.

15. Implant according to claim 4, wherein the implant is arranged with a minimum diameter that is 1 - 5% greater than the diameter of the hole in the bone substance.

All of these claims purport to depend ultimately from claim 1, which claims an implant. These claims, however, do not limit the implant. They specify some intended *use* of the implant, and attempt to limit the implant *based on the characteristics of the bone of a patient.* This is improper under 35 U.S.C. 112, second and fourth paragraphs.

Likewise, these claims are invalid under the second paragraph of Section 112, because they are vague and it is not possible to determine whether they are infringed. For instance, suppose a manufacturer were to prepare an implant having a diameter of 4 mm. Does that implant infringe claim 6, as envisioned by the applicant? It is impossible to know – infringement depends on determining the size of a hole that a dentist might drill later. According to the way the claim purports to read, the implant might infringe one minute but not the next, if the dentist enlarges the hole.

What if the patient is unknown to the manufacturer? What if the implant is manufactured today, but used next year on a patient that presently has all of his natural teeth? Could the implant manufacturer tell whether any of these claims are infringed? Again, it is never possible to tell – the characteristics of an unknown patient or the conduct of the dentist must be determined. These claims do not provide the proper notice function under Section 112 and are invalid for this reason as well.

IV. THE CLAIMS ARE INVALID OVER THE PRIOR ART

The prior art is replete with innumerable varieties of dental implants. The claims of the present application are invalid over the prior art, as set forth below.

A. The claimed implants

The claims define a dental implant. While the claims are verbose, most of the language used in each claim is generally applicable to most or all dental implants, and much of the rest of the claim language is functional language that does not add to the claim. The claims specify the following features: (1) a threading with a slight conicity; (2) "tight threading" of the spirals; (3) multiple thread spirals; and (4) a front portion with a conicity that exceeds the conicity of the thread. Some of the dependent claims specify a fifth feature, eccentric threading.

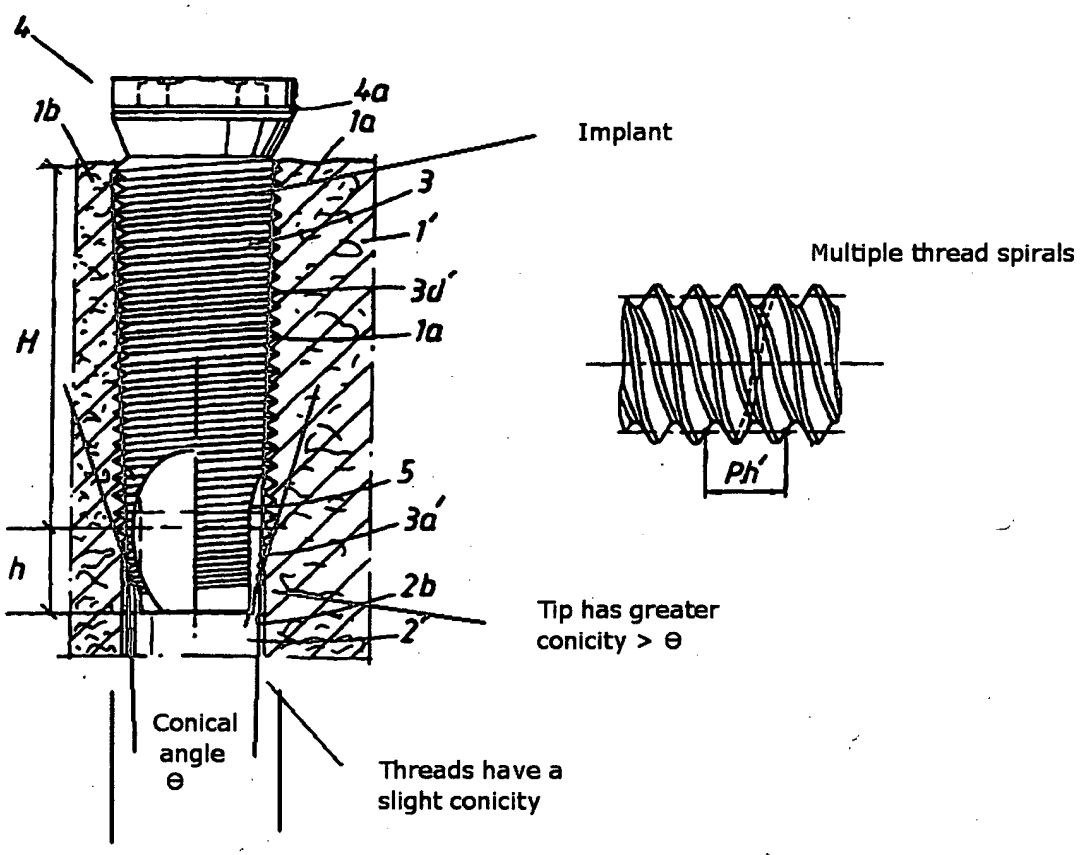
The "slight conicity" refers to threads that are disposed in a frustoconical region along some of the length of the implant. Evidently, the conicity can be obtained in different ways, including a change of diameter of the whole thread profile, change of bottom diameter of thread, or change of outer diameter of thread. The "greater conicity" of the tip appears to describe a frustoconical tip having a conical angle that is greater than the conical angle of the threaded portion. The multiple thread spirals refer to the number of threads on the exterior surface of the implant. Eccentric threading appears to relate to the configuration of the shaft, thread design or a combination thereof.

As to the "tight" threading, this term has no discernable meaning, as discussed above. Nonetheless, the applicant admits in the specification that tight threading is known in the art to be beneficial:

> From the known methods it is already known that good long-term results are obtained if the osseointegration between the bone and the implant can take place with a tight profile and the small pitch of the threads in question.

'869 specification at p. 2.

The following figures (adapted from the patent drawing) illustrate the claimed features (except tight threading, which again is not understood):



Claim 16 is similarly worded and specifies an implant with at least four thread spirals (but this claim does not specify a front portion with greater conicity).

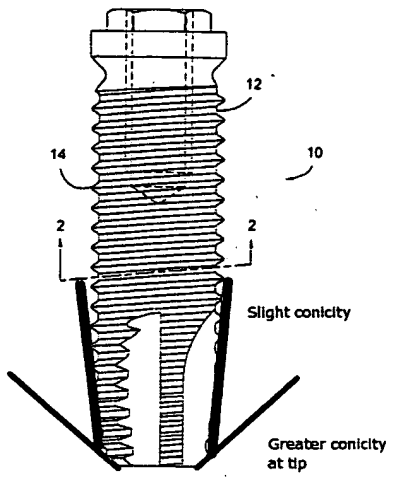
All of the above features have long been known in the implant art. They are common, ordinary features of dental implants. Under *KSR*, the combination of old, known features to attain an unsurprising result is not patentable. *KSR* instructs that "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one." 550 U.S. at __. *KSR* further provides that

> If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. The Court further instructed that "a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.*

B. The claims are invalid over Reams, alone or in view of Zuest

Reams is prior art at least under Section 102(e). The Reams patent discloses an implant that has a slight conicity along a portion of the implant, and a threaded tip with greater conicity. Because "tight" threading is undefined in the present specification, it is meaningless to attempt to determine whether Reams discloses tight threading. It is noted, though, that the threading of Reams has a similar appearance to the threading of the present application – to the extent that "tight" is asserted to have any meaning at all, it would appear that Reams discloses such threading. Figure 1 from the Reams patent is reproduced below:



Reams thus discloses an implant with a slight conicity extending along part of the implant. In this respect. Reams teaches, at column 2 ll. 19-26, that the implant "may employ these and other characteristics variably according to the invention." Reams further provides that the "variation employed" can be "synchronous or *it can progress or regress with respect to the axis* as its proceeds along the axis from one end of the body toward the other end." Examples of this variation include

- an implant with an irregular progressive thread bottom diameter;

- an implant with an irregular progressive external thread (top) diameter;

- a combination of the above, thus resulting in an irregular progressing thread with a constant height (since both thread bottom and top diameter could have the same progress) and thus ending up with a slightly conical thread profile.

The Reams patent also teaches multiple threads. For instance, in claim 1, Reams provides that the implant includes "*at least* one thread making a plurality of turns around said elongated body." This constitutes a teaching of a multi-threaded implant – the implant can have more than "one thread making a plurality of turns."

The Reams patent also discloses an implant with an eccentric threaded surface. See Fig. 2, reproduced below.

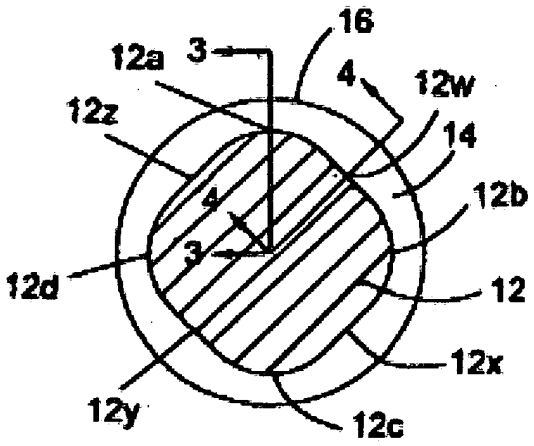


FIG. 2

The Zuest publication (as do many others) discloses an implant with multiple lead threads, and recognizes the advantages of using such lead threads. For instance, at column 19, lines 35-44, Zuest teaches:

> The use of an implant having two or more stabilizing threads on the outer surface of the stem embedded in the jawbone, combined with the inverted cup shape of the lower end of the implant, provides a stable implant which resists movement even in the case of the very short version. Bone growth into the inverted cup and between the threads provides a large area of bone to implant contact and osseointegration, providing significant resistance to

both lateral and downward forces both during and after the osseointegration period.

Zuest and Reams are fairly combinable because they are in the same field (dental implants) and they seek the same result (a stable implant).

All features of the claimed invention are found in the Reams patent, as illustrated in the chart below. Zuest is provided as reinforcing the teachings of Reams in respect of multiple threads. As discussed above, the claims that purport to define the implant with respect to third party bone structure (e.g., claim 14) are so indefinite that it is not possible to attempt to map the claim onto any prior art implant, or any potentially infringing implant for that matter.

1. Threaded implant for obtaining reliable anchoring in bone substance, the bone substance being provided with a hole in whose side wall an internal threading may be established which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance,	These features are common to many implants, and this limitation is met by Reams.
wherein the implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole,	This is non-limiting functional language. In any case, any implant that is placed in a bone bore having a smaller diameter than the diameter of the implant will force the bone out in the radial direction to at least some extent, even if it is a self-tapping implant.

that the implant threading has a slight conicity which extends along most or part of the length of the implant and which cooperates with a circular cylindrical hole in the bone substance to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole,	Reams discloses the slight conicity along part of the length of the implant. This is illustrated in the figures. Reams also teaches that the variation can be one or a combination of many configurations that relate to thread design and that the "variation employed"... "can progress with respect to the axis." This is an express teaching of conicity. The rest of the language is nonlimiting functional language.
the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring,	This language is vague. Reams discloses an implant that can be reliably anchored in bone.
and that said conical threading comprises two or more thread spirals which provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking –up of fine bone trabeculae which surround the hole in the bone,	"Tight" threading is admitted by the applicant to be in the prior art. Reams may or may not disclose tight threading – it is impossible to tell because "tight" is undefined in this specification. The threading on Reams is similar in appearance to the threading depicted in the present application. Reams teaches multiple thread spirals (claim 1 specifies "at least one thread making a plurality of turns around" the implant body). Also, multiple threads are disclosed by Zuest.

and wherein the front portion of the implant is designed with a conical thread which has a conicity exceeding the conicity of the slightly conical thread.	Reams teaches an implant with greater conicity at the "front portion"; *see* Fig. 1, *supra.* As seen therein, the distal end or "front portion" has a conicity that exceeds the conicity of the slightly conical thread.
2. Implant according to claim 1, wherein the implant threading is arranged to ensure that the pressure between the bone substance and the implant has essentially a constant or slightly increasing value during the greater part of the operation of screwing the implant into the hole.	See Reams, Fig. 7, which teaches an increasing torque as the implant is screwed into a test hole.
4. Implant according to claim 1, wherein the conicity of the slightly conical thread is chosen between 0.1 – 0.4 mm or has an angle of inclination of about 0.5 - 2°, an/or the thread conicity of the thread at the said front portion of the implant is of the order of 0.4 – 0.8 mm or with an angle of inclination of about 10 – 15°, and the front portion of the implant has a length or height of about 10 – 30% of the length of the threaded part of the implant.	This is simply an attempt at optimizing the parameters already disclosed by Reams and the common usage applied in the field of tolerances within or close to the claimed parameters. There is nothing patentable about merely optimizing the dimensions of the prior art to suit a particular purpose. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (C.C.P.A. 1955).

5. Implant according to claim 1, wherein the implant threading along at least part of the longitudinal direction of the implant is given a noncircular or eccentric configuration for the purpose of obtaining improved rotational stability of the implant in the recently inserted state or the incorporated state of the implant in the bone substance.	This feature is shown in Reams.
7. Implant according to claim 1, wherein the front portion of the implant has a circular or concentric thread which merges gradually into a non-circular or eccentric thread on the remaining part or parts of the implant.	This is shown by Reams.
8. Implant according to claim 7, wherein the peripheries of the different non-circular or eccentric thread cross-sections have bevelled corners.	See Reams, Fig. 2
9. Implant according to claim 7, wherein the non-circularity is arranged such that areas of maximum diameter are displaced in the peripheral direction from one thread turn to the next thread turn.	See Reams, Fig. 2
10. Implant according to claim 1, wherein the number of thread spirals is two, three or four.	Reams discloses plural thread spirals as discussed above. Zuest discloses two, three, or four spirals. Col. 15 ll. 26-29

16. Threaded implant for obtaining reliable anchoring in bone substance, the bone substance being provided with a hole in whose side wall an internal threading may be established which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance,	These features are common to essentially all implants.
wherein the implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of the length of the implant and which cooperates with a circular cylindrical hole in the bone substance to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole,	See claim 1.
the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals which provide a tight threading which permits effective integration with the bone substance during the healing-in process and	See claim 1.

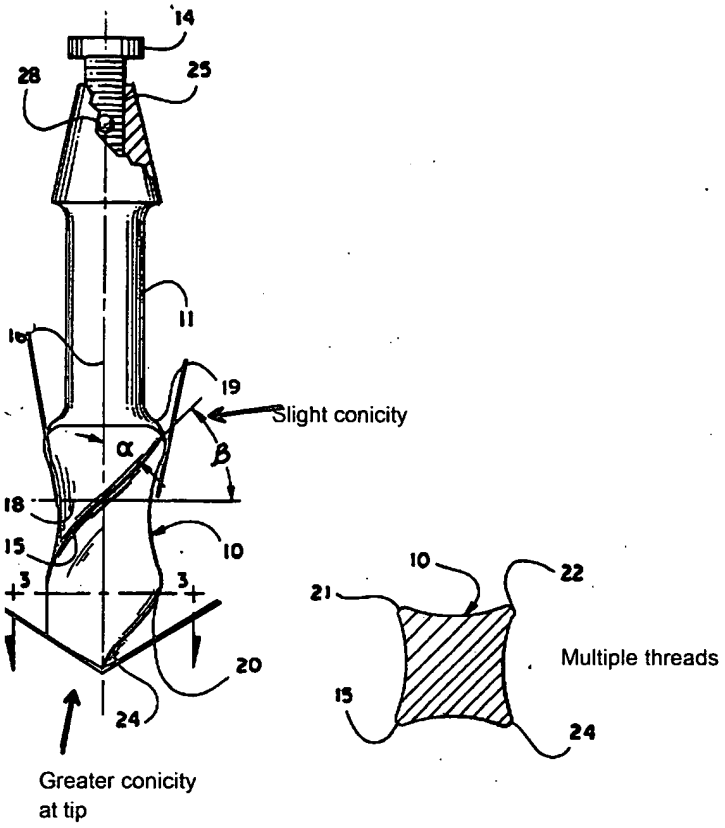
counteracts deformation or breaking-up of fine bone trabeculae which surround the hole in the bone, wherein four thread spirals area arranged together with four cutting edges.	

It is seen that the claims are invalid over Reams alone. The claims likewise are unpatentable over the combination of Reams with Zuest.

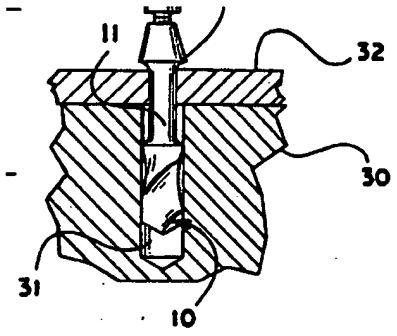
C. The claims are unpatentable over James, U.S. Patent 5,269,686

The James patent issued on December 14, 1993, and hence constitutes prior art to the '869 application under 35 U.S.C. 102(b). The James patent is not presently of record in the subject application.

This patent discloses an implant with multiple threads (four are illustrated). A portion of the threaded region of the implant has a slight conicity. The tip of the implant has a greater conicity than the conicity of the threaded portion. Reproduced below are two figures from the James patent:



This arrangement of multiple threads and conical regions provides a structure for insertion into the bone by driving the implant rigidly into place, as shown in the following figure of the James patent.



As to "tight" threading, given the vagueness in the claim language, it cannot be determined whether the James patent discloses this feature. To the extent that James does not disclose this feature, the applicant has admitted that tight threading is known in the art.

The James patent is strong prior art to the '869 claims. It recognizes the benefits of multiple threads, and discloses an implant with four threads. James depicts threading

having a slight conicity and a tip with greater conicity. Also, the James patent recognizes that the "crests of the threads" will engage the bone when the implant is driven into place (Col 2, line 68 – Col 3, line 2).

It is unclear whether the configuration of James would result in "greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole." Note the proximal portion of the implant and the sizing relative to the distal portion. Nonetheless, the Examiner has recognized this language as functional language that does not limit the claim. *See* Office Action of April 18, 2003 ("With regard to the recitations of . . . how the degree of forcing out is related to the softness of the bone, such recitations are purely functional in nature, and have not been given any weight in the claim").

Also, the applicant argued that the prior art (specifically O'Brien, U.S. Patent 5,527,183) did not disclose plural spiral threads on a conical section of the implant (see amendment of November 20, 2002). This feature is present in the James patent, and the James patent controverts applicant's assertions about the prior art. To the extent that the James patent is not anticipatory for this reason, the claims are obvious over James in view of O'Brien.

For claims 1, 2, 4, 10, and 16, a claim chart showing how James anticipates the claims, or renders them obvious, is attached. The claims that specify eccentric threads are not asserted to be anticipated by James (such claims are obvious over James in combination with other references, such as Reams). Again, claims that have no meaning because they purport to be defined in relation to an external bone structure are not possible to analyze, and are omitted from the chart below.

1. Threaded implant for obtaining reliable anchoring in bone substance, the bone substance being provided with a hole in whose side wall an internal threading may be established which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance,	This language is common to essentially all prior art implants. The implant of James possesses these features.

Wherein the implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole,	This is non-limiting functional language.
that the implant threading has a slight conicity which extends along most or part of the length of the implant and which cooperates with a circular cylindrical hole in the bone substance to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole,	James discloses the slight conicity along part of the length of the implant. The rest of the language is nonlimiting functional language.
the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring,	This language is vague. James discloses an implant that can be reliably anchored in bone.
and that said conical threading comprises two or more thread spirals which provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking –up of fine bone trabeculae which surround the hole in the bone,	James discloses multiple thread spirals. "Tight" threading is admitted by the applicant to be in the prior art. James may or may not disclose tight threading – it is impossible to tell because "tight" is undefined in this specification.

and wherein the front portion of the implant is designed with a conical thread which has a conicity exceeding the conicity of the slightly conical thread.	James discloses this feature. The distal end or "front portion" has a conicity that exceeds the conicity of the slightly conical thread (*see* figure, *supra*).
2. Implant according to claim 1, wherein the implant threading is arranged to ensure that the pressure between the bone substance and the implant has essentially a constant or slightly increasing value during the greater part of the operation of screwing the implant into the hole.	James discloses this feature. The configuration of thread spirals results in a pressure that is essentially a constant during the greater part of the operation of screwing the implant into the hole.
4. Implant according to claim 1, wherein the conicity of the slightly conical thread is chosen between 0.1 – 0.4 mm or has an angle of inclination of about 0.5 - 2°, an/or the thread conicity of the thread at the said front portion of the implant is of the order of 0.4 – 0.8 mm or with an angle of inclination of about 10 – 15°, and the front portion of the implant has a length or height of about 10 – 30% of the length of the threaded part of the implant.	This is simply an attempt at optimizing the parameters already disclosed by James. There is nothing patentable about merely optimizing the dimensions of the prior art to suit a particular purpose. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (C.C.P.A. 1955).
10. Implant according to claim 1, wherein the number of thread spirals is two, three or four.	James discloses four thread spirals.
16. Threaded implant for obtaining	These features are common to essentially

reliable anchoring in bone substance, the bone substance being provided with a hole in whose side wall an internal threading may be established which can cooperate with an external threading on the implant for reliable anchoring and healing-in of the implant in the bone substance,	all implants.
Wherein the implant threading is arranged to force the bone substance out in essentially radial directions as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of the length of the implant and which cooperates with a circular cylindrical hole in the bone substance to effect greater forcing out of the bone substance at the outer parts of the hole than at the inner parts of the hole,	See claim 1.
the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals which provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking-up of	See claim 1.

fine bone trabeculae which surround the hole in the bone,	
Wherein four thread spirals area arranged together with four cutting edges.	James discloses four thread spirals.

D. The claims are invalid over these references in view of the art of record

"Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *KSR*, 550 U.S. at __. In this case, all the applicant has done is to gather several well known implant features and consolidate them into a single claim set. Combining known features, which work together in known ways to achieve an expected result, is not an act of invention, and the applicant's efforts here are unworthy of a patent. Under *KSR*, the Examiner "must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at __. In this case, there is no improvement at all, much less does the claimed invention represent anything other than "the predictable use of prior art elements according to their established functions."

The Examiner is referred to the rejections and references of record, in particular the heretofore mentioned O'Brien and Niznick references, for similar implants. These references, and others of record, easily could be combined to form other rejections that are equally applicable to the claimed invention (e.g., James in view of Zuest, Niznick in view of James and Zuest, etc.). Nothing of any patentable significance is seen in this disclosure, and the Examiner is urged to enter a final rejection of the pending claims.

V. CONCLUSION

There is nothing patentable in the present application. All of the claims must be rejected for the reasons presented above.

The Examiner is advised that Fredrik Engman, named as an inventor in the present application, is associated with NEOSS, Inc., the party on whose behalf this Protest is filed.

Respectfully submitted,

Dated: February 12, 2009

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US005269686A

United States Patent [19]

James

[11] Patent Number: 5,269,686

[45] Date of Patent: Dec. 14, 1993

[54] **THREADED DRIVABLE DENTAL IMPLANT**

[76] Inventor: Robert A. James, School of Dentistry, Loma Linda University, Oral Implantology Center, Loma Linda, Calif. 92340

[21] Appl. No.: 58,262

[22] Filed: May 10, 1993

[51] Int. Cl.[5] A61C 8/00

[52] U.S. Cl. 433/174; 433/173

[58] Field of Search 433/173, 174, 175

[56] References Cited

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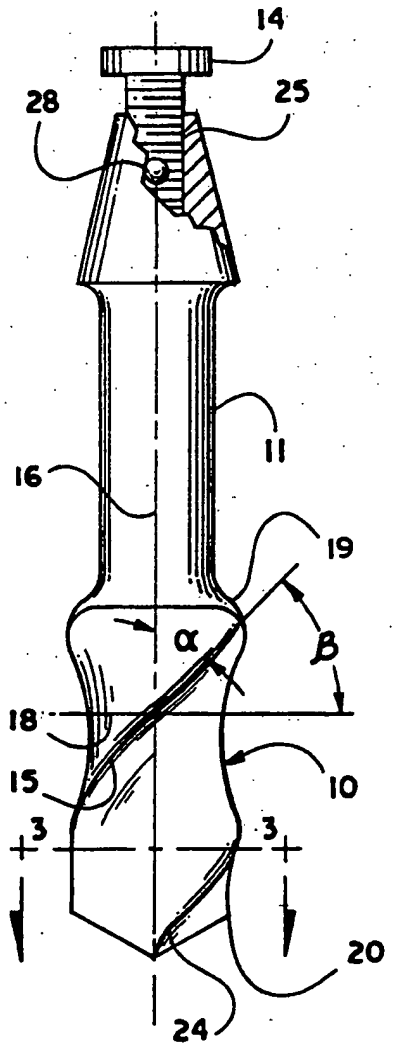
Primary Examiner—John J. Wilson

Attorney, Agent, or Firm—James B. Middleton

[57] **ABSTRACT**

A dental implant has threads with a long pitch so the implant can be driven into a predrilled hole in the bone by axially delivered blows. When rotational forces are placed on the implant in attaching or removing the prosthesis, the long pitch threads will mechanically resist the rotational forces. The implant also includes a post integrally formed thereon so a minimum of separate procedures is required. The post includes a screw having a nylon rod therethrough to lock the screw in place.

12 Claims, 1 Drawing Sheet



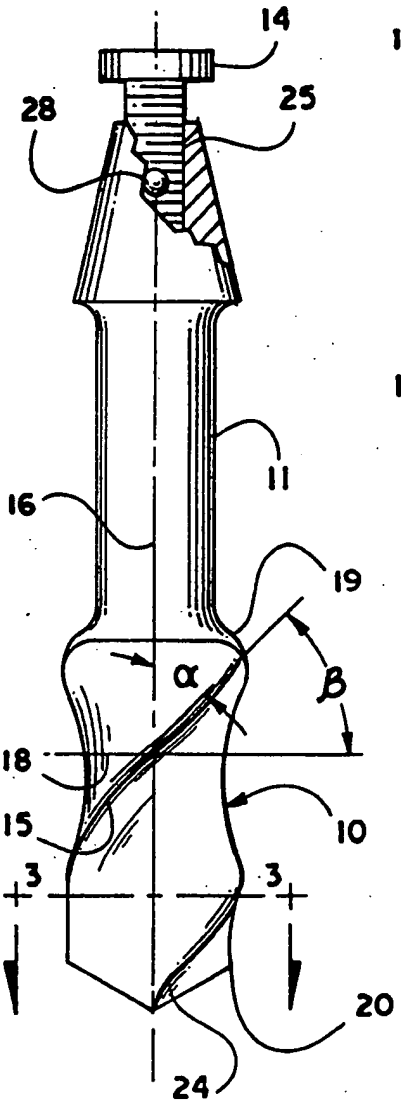


Fig_1

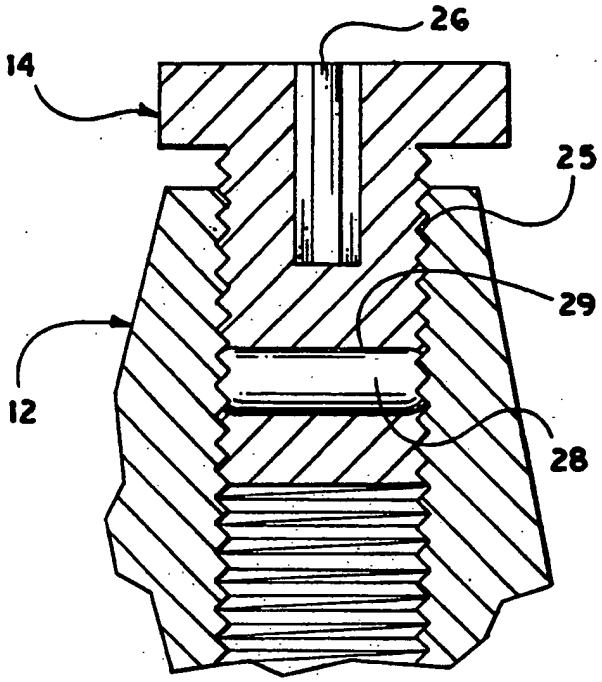


Fig_2

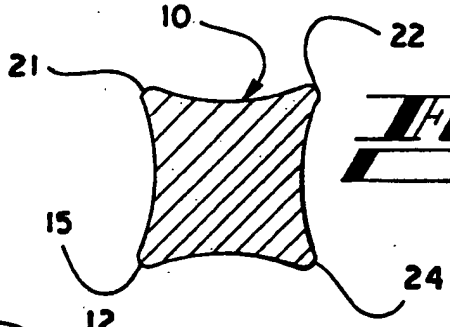


Fig_3

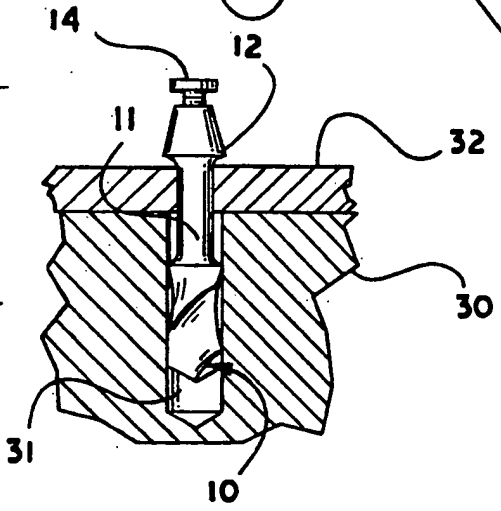


Fig_4

THREADED DRIVABLE DENTAL IMPLANT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to dental implants, and is more particularly concerned with a drivable implant having torque resisting means.

2. Discussion of the Prior Art

When one or more teeth are to be replaced, it is a common practice to anchor the tooth or teeth prostheses to adjacent teeth. As long as the adjacent teeth are well seated in and secured by bone, the use of adjacent teeth to anchor a prosthesis works quite well. There are, however, times when the adjacent teeth are not sufficiently secure to endure the additional stress encountered in anchoring a prosthesis. In such events, the common practice is to install an implant having a post for securing the prosthesis. The implant is installed by drilling a hole into the bone, and inserting the implant into the bone. A post is then connected to the implant, and the prosthesis is attached to the post, usually by means of a threaded screw. The prosthesis can be installed and removed as desired, and this is done primarily during the fitting stages.

The prior art implants have taken two different forms. In one form, the implant includes a generally straight shank that is driven into the hole in the bone, by tapping with a mallet or the like. This driven implant has the advantage that the implant is quickly placed and is relatively nontraumatic to the bone. The disadvantages of the driven type implant are the fact that only frictional force secures the implant to the bone at the initial installation; and, the driven implant has minimal surface for subsequent tissue attachment. The advantages of the screw-in implant are that the implant is literally screwed into the bone, cutting its own threads in the process, so the screwed-in implant is very secure mechanically on initial installation. Further, the screwed-in implant has a very large surface area because of the threads, and this large surface area promotes attachment of tissue. The primary disadvantage of the screw-in implant is the trauma to the bone caused by the stresses of threading the implant into the drilled hole.

A further difficulty with both the above mentioned types of implants is the likelihood that the implant will be broken loose from its attachment during manipulation of the screw that holds the prosthesis. The driven-in implant has no mechanical means to prevent rotation of the implant, relying only on frictional force and tissue attachment. Both of these can be relatively easily overcome in attempting to remove a screw, especially if the screw has been in place for some time. The screwed-in implant has threads, and will also have some tissue attachment; but, attempting to remove a screw holding a prosthesis can unscrew the screwed-in implant. In either case, it will be understood by those skilled in the art that, once the implant has been broken loose from the tissue attachment, the implant must be removed and replaced.

SUMMARY OF THE INVENTION

The present invention provides a dental implant to be received within a hole drilled in the bone. The lower portion of the implant includes a thread having a long pitch, the crest of the thread forming a small acute angle with a line parallel to the direction of movement of the implant. With the angle of the thread relatively steep, it will be understood that the implant can be driven into the predrilled hole, but will rotate slightly. As the implant is driven into the hole, the crests of the threads will thread themselves into the bone. It is important to note that, if a rotational force is then placed on the implant, the rotational force being about the centerline of the implant, the thread will form a large angle with a line parallel to the direction of motion, so the thread will offer mechanical resistance to rotation of the implant.

In the preferred form of the invention, the threads on the implant comprise a multiple thread to provide balance in the implant. Further, the post is made integrally with the implant, and a screw having a locking means is provided with the implant.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will become apparent from consideration of the following specification when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a front elevational view showing an implant and integral post made in accordance with the present invention, a portion thereof being broken away to illustrate the construction;

FIG. 2 is an enlarged, fragmentary view showing the screw for attachment of the prosthesis;

FIG. 3 is a cross-sectional view taken substantially along the line 3—3 in FIG. 1; and,

FIG. 4 is a front elevational view of the implant shown in FIG. 1, but on a reduced to scale, and shown implanted for use.

DETAILED DESCRIPTION OF THE EMBODIMENT

Referring now more particularly to the drawings, and to that embodiment of the invention here presented by way of illustration, the device shown in FIG. 1 includes an implant designated at **10** and a neck portion designated at **11**. Carried on the neck portion **11** is a post **12**, the post **12** having a screw **14** threaded thereinto. It is common in the prior art to provide an implant **10** to be implanted into the bone, and to require that a post, such as the post **12**, be subsequently attached to the implant. A prosthesis is then fixed to the post by a screw or the like, such as the screw **14**. The present invention therefore simplifies the entire procedure by making the implant **10** integral with the post **12**. Of course the screw **14** must remain for use as a fastening means to fix a prosthesis to the post **12**.

Looking more specifically at the implant **10**, it will be seen that the implant **10** includes threads **15**. The threads **15** have a very long pitch, which is to say there is a large distance between adjacent crests of a thread. The important aspect of the long pitch is that the angle a between the crest of the thread **15** and the centerline **16** of the implant **10** is relatively small. When the implant is being driven in, the direction of the force will be along lines that are parallel to the centerline **16**.

It will be understood that, if the angle α were zero the threads **15** would amount to longitudinal ridges on the implant, and if the angle α were 90° the threads **15** would be concentric rings around the implants. Thus, by making the angle α greater than zero but very small, a thread is achieved that will allow the implant to be driven into a predrilled hole. Since the crests of the

threads 15 will engage the bone as the implant is driven in, the implant will rotate and the implant will cut its own threads into the bone. The specific angle α is somewhat variable, but it is preferred that the angle be around 20° to 25°, though the angle α may be as large as about 30°.

When a rotational force is placed on the implant, the force being about the centerline 16, threads 15 will counteract the force. In this direction, one must consider the angle β which is the angle between the thread 15 and a perpendicular 18 to the centerline 16, which is also parallel to the direction of the force applied on the implant. If the angle β is very small, the rotational force will be almost along the ridge of the thread, but if the angle β is large, the rotational force will be approaching a perpendicular to the crest of the thread. It will be recognized that, if the angle α is 20°, the angle β will be 70°, the angles being complementary.

With the long pitch threads here contemplated, it will be readily understood that, in a conventional length of implant, there would probably be only a single thread. As a result, in order to balance the implant, and render the device more stable, it is contemplated that a multiple thread will be used. In the embodiment here presented by way of illustration, a quadruple thread is utilized as is best shown in FIG. 3 of the drawings. Looking at FIG. 1 in conjunction with FIG. 3, it will be understood that the four separate threads begin at the top 19 of the implant 10, and each of the threads 15 extends helically down to the lower end 20 of the implant 10. There are therefore four crests of threads designated at 15, 21, 22 and 24.

Turning now to the post 12 shown in FIG. 1 of the drawings, and looking also at FIG. 2 of the drawings, it will be seen that the post 12 is a generally frustoconical member here shown as formed integrally with the neck 11. The post 12 defines a threaded opening 25 for selectively receiving the threaded screw 14. As is known in the art, the screw 14 includes a hexagonal socket 26 to receive an Allen wrench for rotation of the screw 14.

Those skilled in the art will realize that, sometimes screws such as the screw 14 will become loose after the prosthesis has been put into place and the screw tightened. The loosening is due to normal cyclic forces on the prosthesis. In an effort to counteract these forces and hold the screw 14 in place, the present invention includes a locking means 28. The locking means 28 comprises a deformable rod received within a hole 29 that extends diametrically through the screw 14. The rod 28 will normally protrude slightly beyond the threads on the screw 14 so that, when the screw 14 is received within the threaded opening 25, the rod 28 will be deformed by the threads. The rod 28 therefore serves to jam the screw 14 into place. The rod 28 may be made of any one of numerous materials, such as nylon or other plastic elastomeric materials, or may be made of natural or synthetic rubber or the like.

With the foregoing description in mind, attention is directed to FIG. 4 of the drawings. FIG. 4 illustrates a device of the present invention as it would be installed. The bone into which the implant is installed is designated at 30, the bone 30 defining a drilled hole 31 therein. It will be seen that the implant 10 is received completely within the hole 31, and the neck 11 extends through the hole 31, then through the gum tissue 32. The post 12 is above the gum 32 for receipt of the prosthesis. The gum 32 is here shown as closely surrounding the neck 11, and it will be understood that this will be the situation after the implant has been installed and the soft tissue has healed.

When a prosthesis is to be installed on the post 12, the screw 14 will be removed, and the prosthesis will be put into place on the post 12. The screw 14 will then be replaced and firmly tightened. When the screw 14 is tightened, it will be understood that a rotational force will be applied on the implant 10. Due to the angle of the thread 15, it will be understood that there will be a great force resisting rotation of the implant 10 so the implant 10 is unlikely to rotate within the hole 31. If the prosthesis must then be removed for further fitting or the like, removal of the screw 14 will require a rotational force on the implant in the opposite direction. In this case, the thread 15 will also present a large counteracting force so that the implant 10 is unlikely to be rotated.

After the implant has been in place for a period of time, tissue will attach to the implant and assist in resisting rotation. After attachment of the tissue, if the implant is caused to rotate, the tissue will be destroyed and the implant must be removed and replaced. In the present invention, the mechanical arrangement is such that there is mechanical force that protects the tissue growth so that the implant is unlikely to fail and have to be removed. Further, due to the additional surface area caused by the presence of the multiple threads, it will be understood that there will be a considerable amount of tissue attachment to the implant of the present invention.

Those skilled in the art will understand that the implants of the present invention can be made in numerous sizes, and with various thread arrangements. By way of illustration without any intent to limit the scope of the present invention, one successful embodiment of the invention has a major diameter on the implant of about 3.5 millimeters and a threaded length of around 7 to 13 millimeters. In this embodiment, the threads have a pitch of one thread per inch (1 thread in 25.4 mm), and there are four threads.

From the top of the thread to the bottom of the post might be around 8 millimeters, and the post itself may be around 4 millimeters high. The implant of the present invention has been made of a conventional titanium alloy as is well known for use in dentistry, but those skilled in the art will readily select other materials that serve as well.

It will therefore be understood by those skilled in the art that the particular embodiment of the invention here presented is by way of illustration only, and is meant to be in no way restrictive; therefore, numerous changes and modifications may be made, and the full use of equivalents resorted to, without departing from the spirit or scope of the invention as outlined in the appended claims.

I claim:

1. A dental implant to be received within a hole drilled into the bone, said dental implant including a lower threaded portion having an axis, and an upper neck portion, said lower threaded portion and said neck portion being coaxial, said lower threaded portion including at least one thread extending throughout said lower threaded portion and including a crest of said thread, said crest of said thread forming an acute angle of no more than 30° with said axis, so that said implant is adapted to be driven into said hole drilled into the bone by forces exerted axially of said implant.

2. A dental implant as claimed in claim 1, wherein said acute angle is from 20° to 25°.

3. A dental implant as claimed in claim 1, said at least one thread comprising a multiple thread, the threads of said multiple thread being uniformly spaced around said implant.

4. A dental implant as claimed in claim 3, said multiple thread comprising four threads.

5. A dental implant as claimed in claim 1, said implant further including a post carried on said neck portion, the dimensions of said implant being such that said threaded portion will be received within said hole drilled into the bone, said neck portion will extend from said hole to above the gum line, and said post will be disposed above said gum line.

6. A dental implant as claimed in claim 5, said post defining a threaded recess therein, a screw threadedly receivable within said recess, and locking means for securing said screw within said recess.

7. A dental implant as claimed in claim 6, said screw defining a bore laterally therethrough, said locking means comprising a deformable rod received within said bore and engageable with the threads in said threaded recess.

8. A dental implant as claimed in claim 7, wherein said rod consists of a thermoplastic elastomer.

9. A dental implant, of the type wherein a hole is drilled into the bone for receiving the implant, and the implant carries a post above the gum line for attachment of a prosthesis, said implant including a threaded portion to be received within said hole and having an axis, and a neck portion extending coaxially from said threaded portion through the soft tissue, said threaded portion having a multiple thread extending throughout the length of said threaded portion, each thread of said multiple thread being disposed at an acute angle of no more than 30° with respect to said axis so that said implant can be driven into said hole by forces exerted axially of said implant, the arrangement being such that said implant will rotate somewhat under the influence of said threads as said implant threads into said hole.

10. A dental implant as claimed in claim 9, and further including a post carried on said neck portion, the dimensions of said implant being such that said threaded portion will be received within said hole drilled into the bone, said neck portion will extend from said hole to above the gum line, and said post wall be disposed above said gum line.

11. A dental implant as claimed in claim 10, said post defining a threaded recess therein, a screw threadedly receivable within said recess, and locking means for securing said screw within said recess.

12. A dental implant, of the type wherein a hole is drilled into the bone for receiving the implant, and the implant carries a post above the gum line for attachment of a prosthesis, said implant including a threaded portion to be received within said hole, and a neck portion extending coaxially from said threaded portion through the soft tissue, said threaded portion having a multiple thread extending throughout the length of said threaded portion, said multiple thread being at such an angle that said implant can be driven into said hole by forces exerted longitudinally on said implant, the arrangement being such that said implant will rotate somewhat under the influence of said threads as said implant threads into said hole, and further including a post carried on said neck portion, the dimensions of said implant being such that said threaded portion will be received within said hole drilled into the bone, said neck portion will extend from said hole to above the gum line, and said post will be disposed above said gum line, said post defining a threaded recess therein, a screw threadedly receivable within said recess, and locking means for securing said screw within said recess, said screw defining a bore laterally therethrough, said locking means comprising a deformable rod received within said bore and engageable with the threads in said threaded recess.

* * * * *

US005902109A

United States Patent [19]

Reams, III et al.

[11] Patent Number: 5,902,109

[45] Date of Patent: May 11, 1999

[54] **REDUCED FRICTION SCREW-TYPE DENTAL IMPLANT**

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[73] Assignee: **Implant Innovations, Inc.**, Palm Beach Gardens, Fla.

[21] Appl. No.: **08/782,056**

[22] Filed: **Jan. 13, 1997**

Related U.S. Application Data

[60] Provisional application No. 60/010,179, Jan. 18, 1996, and provisional application No. 60/011,034, Feb. 2, 1996.

[51] **Int. Cl.**[6] **A61C 8/00**

[52] **U.S. Cl.** **433/174**

[58] **Field of Search** 433/172, 173, 433/174, 201.1

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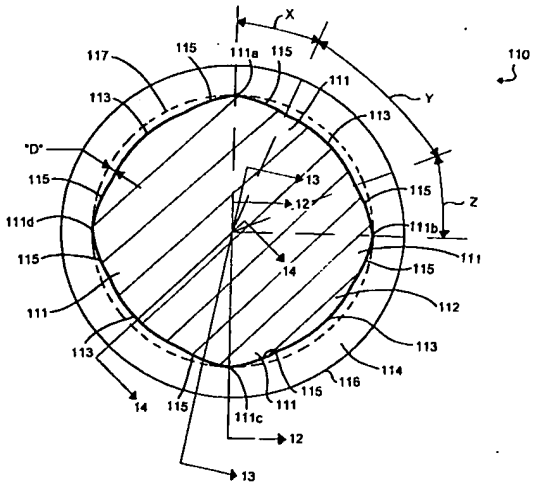
Primary Examiner—Nicholas D. Lucchesi

Attorney, Agent, or Firm—Arnold, White & Durkee

[57] **ABSTRACT**

An implant for implantation into bone tissue having an exterior surface includes an elongated body and at least one thread. The elongated body has a distal end portion for being submerged in the bone tissue, a proximal end portion for being located near the exterior surface of the bone tissue, a central axis, and an outer surface. When viewed in cross-section, the elongated body has a non-circular cross-section. The non-circular cross-section includes a plurality of lobes and a plurality of dwells. Each of the plurality of dwells is disposed between adjacent ones of the plurality of lobes. The thread extends radially outward with respect to the central axis from the outer surface of the elongated body between the distal end portion and the proximal end portion. As the implant is screwed into the bone tissue, only the lobes on the elongated body engage the bone tissue. Because no contact exists between the dwells and the bone tissue, the amount of torque required to insert the implant is reduced.

45 Claims, 8 Drawing Sheets



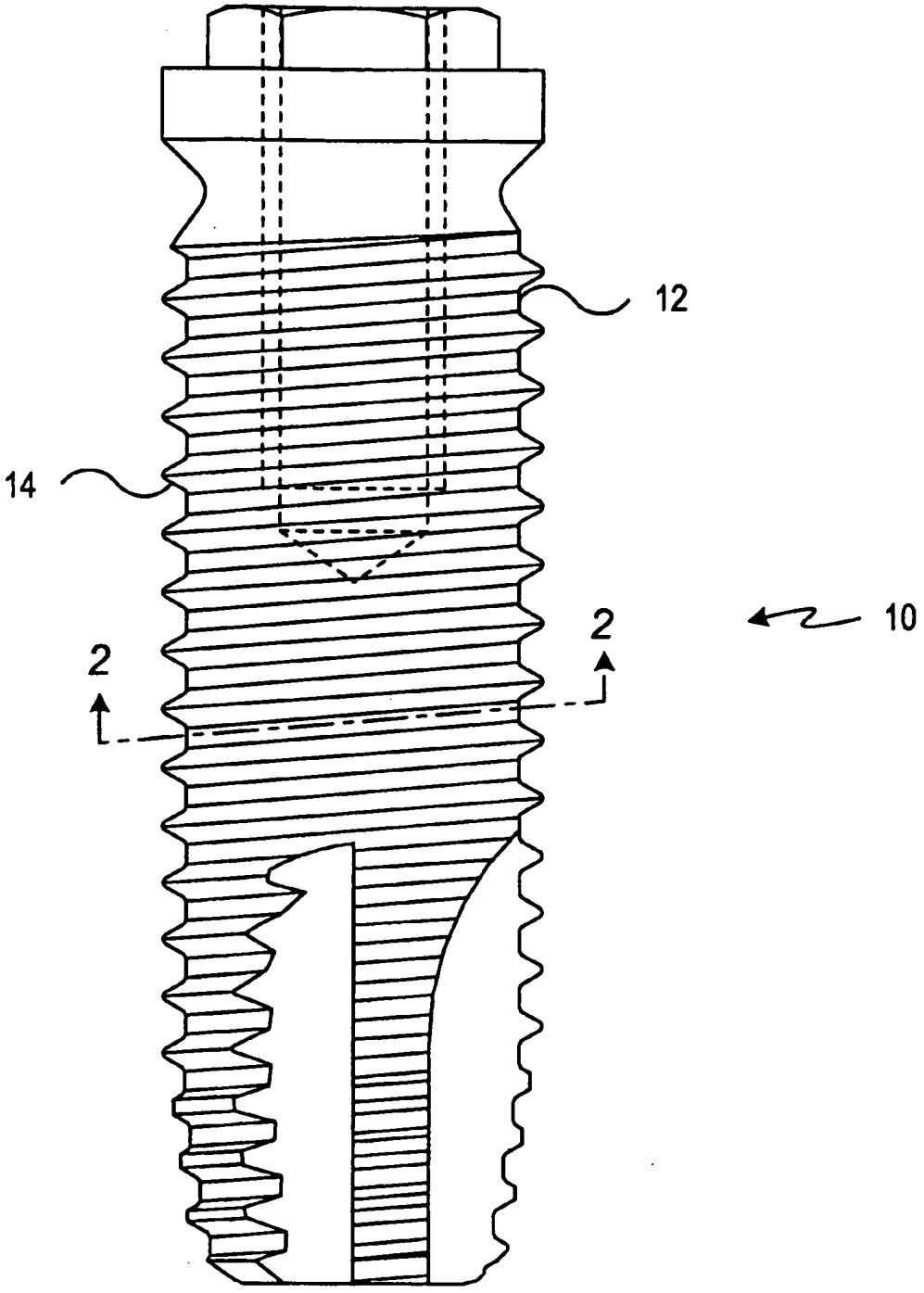


FIG. 1

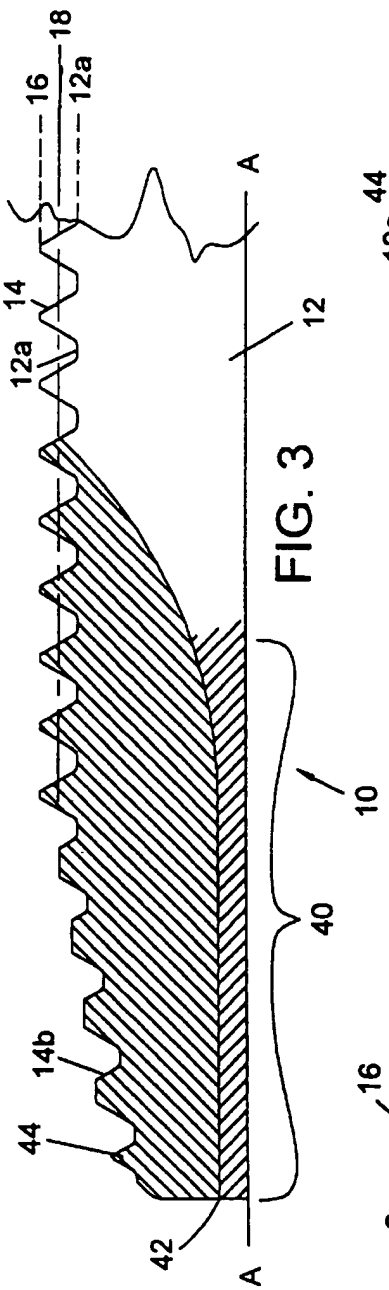


FIG. 3

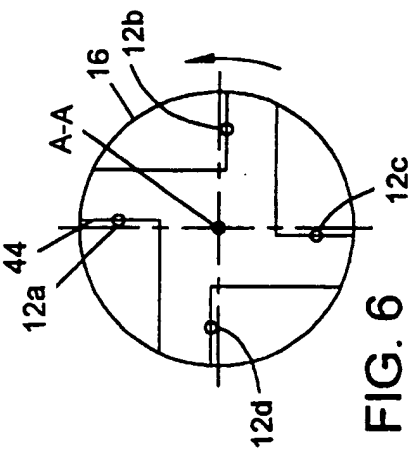


FIG. 6

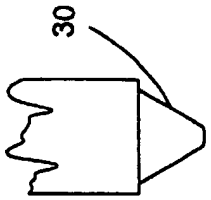


FIG. 5

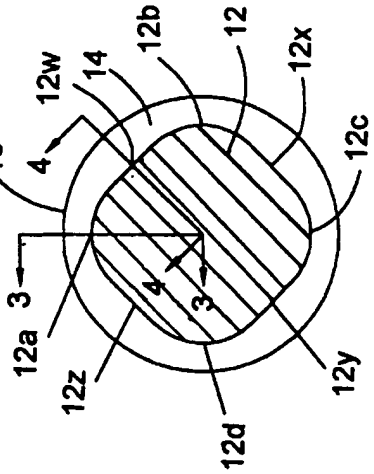


FIG. 2

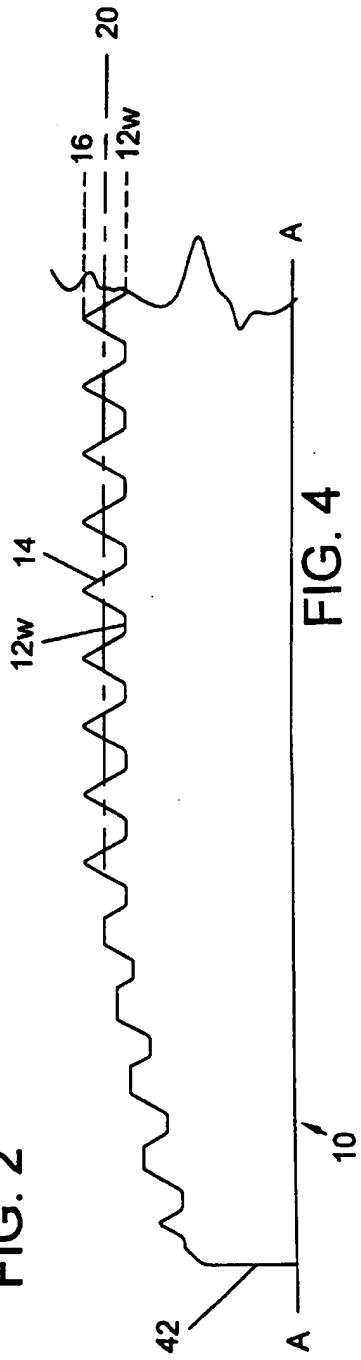
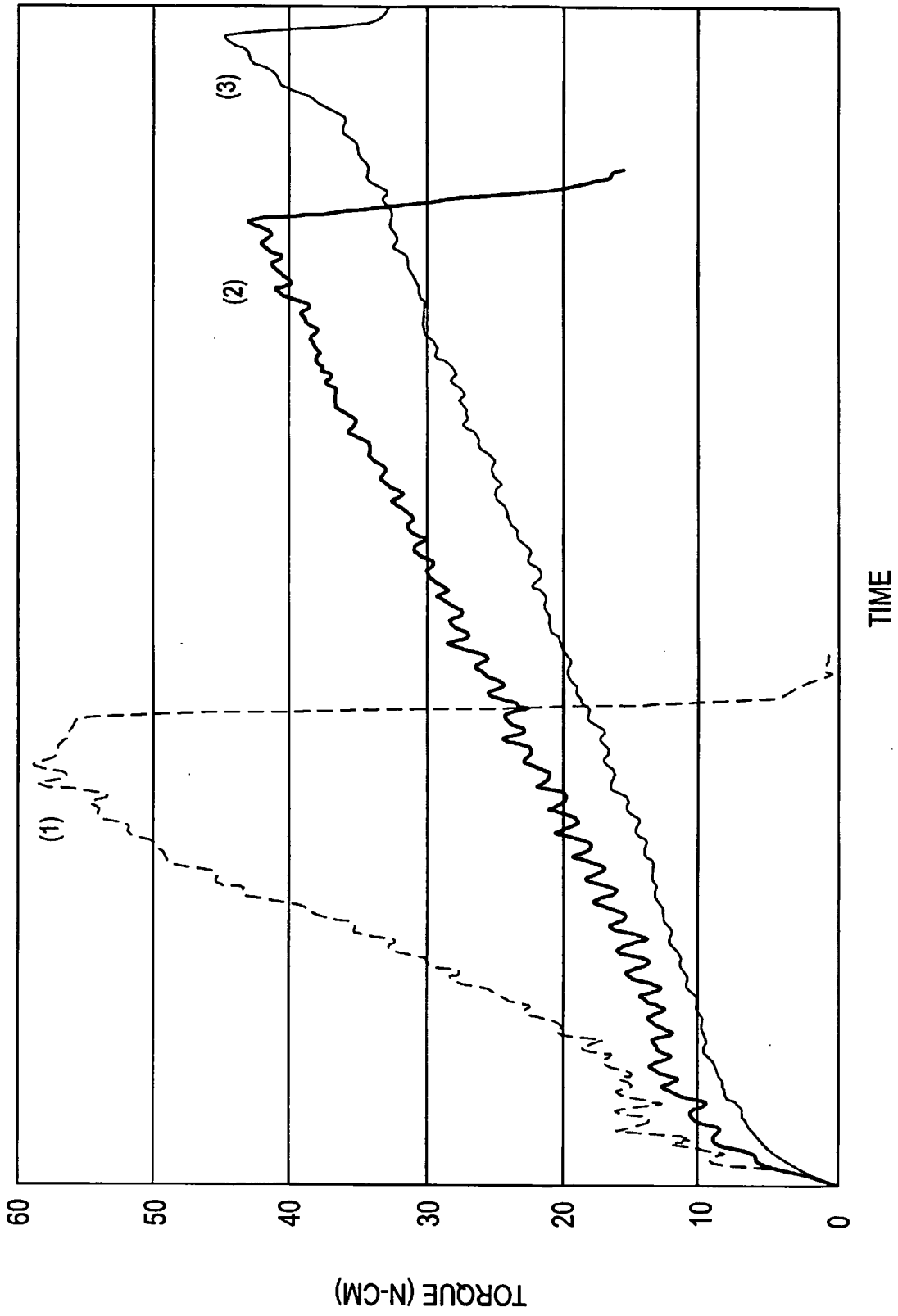


FIG. 4

FIG. 7



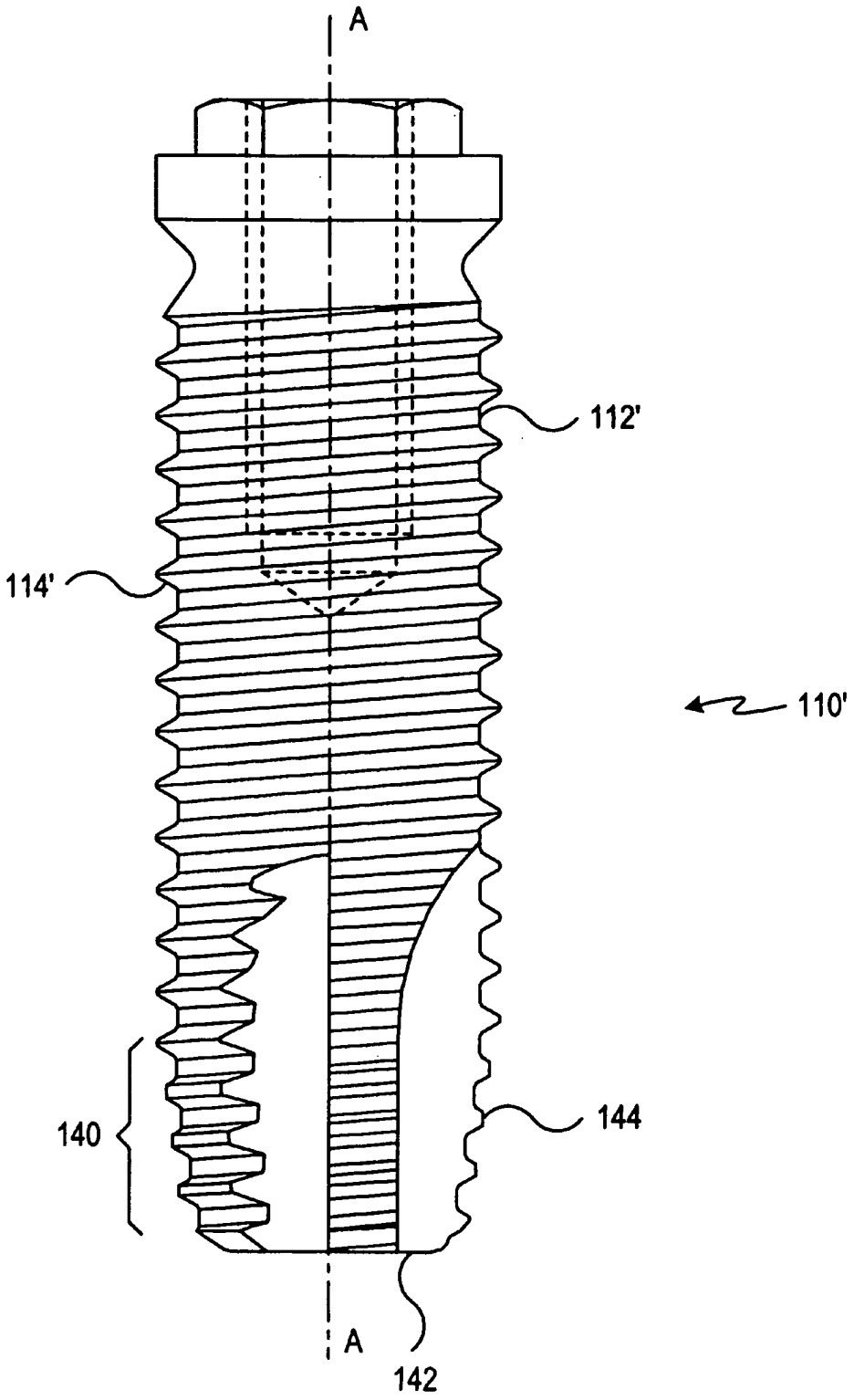


FIG. 8

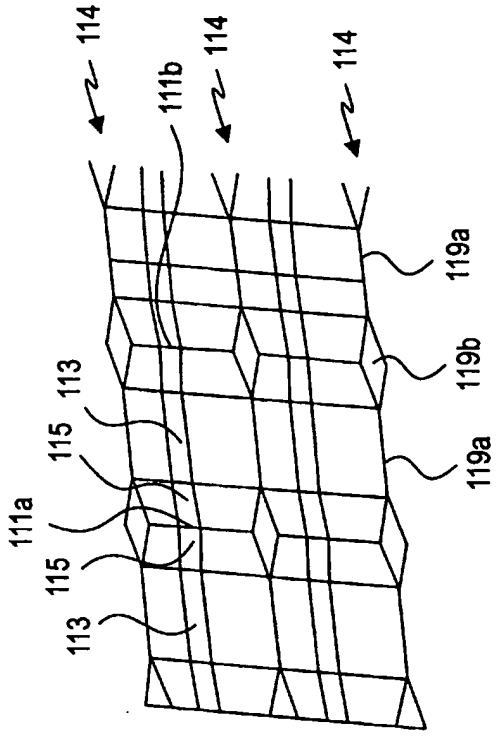

114
111b
114
114
119a
119b
119a
113
115
111a
115
113

FIG. 10

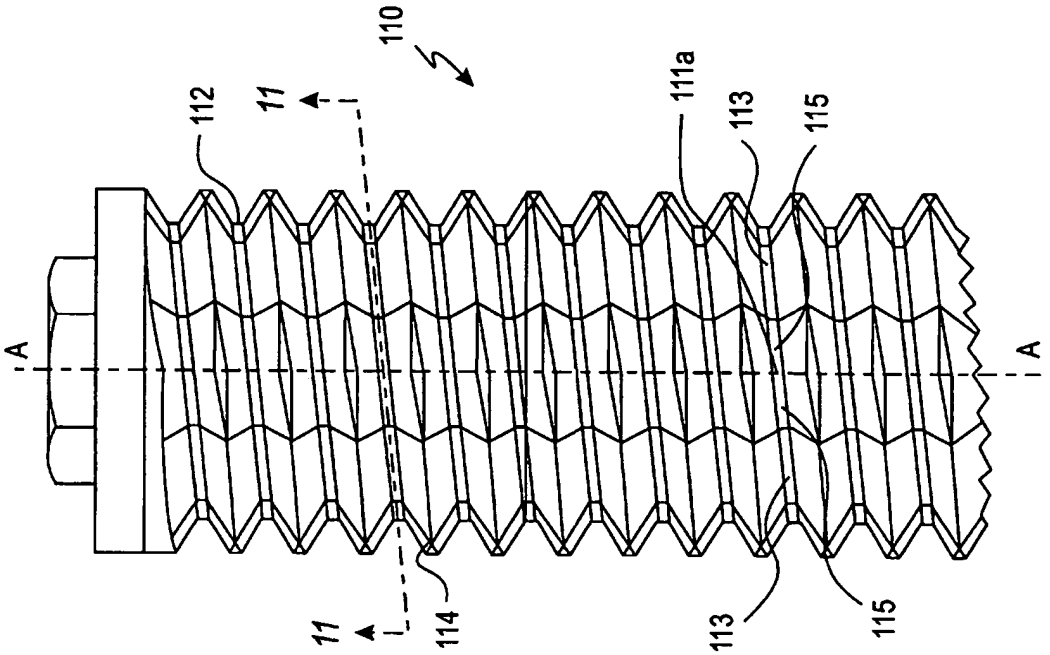
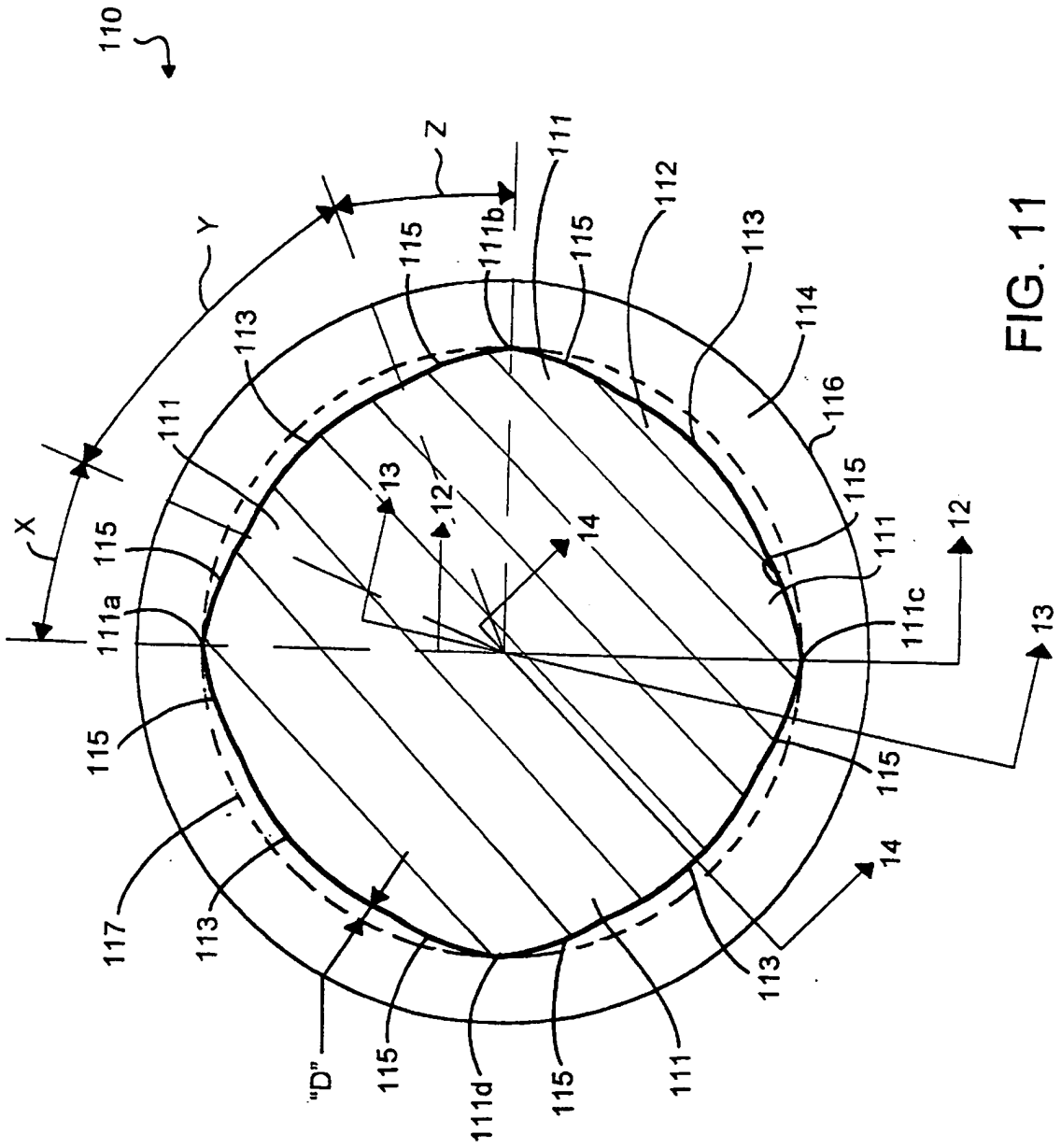

110
112
11
111a
113
115
A
A
11
114
113
115

FIG. 9


110
Z
Y
X
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111b
111a
111c
111d
112
113
114
115
116
117
12
13
14
"D"

FIG. 11

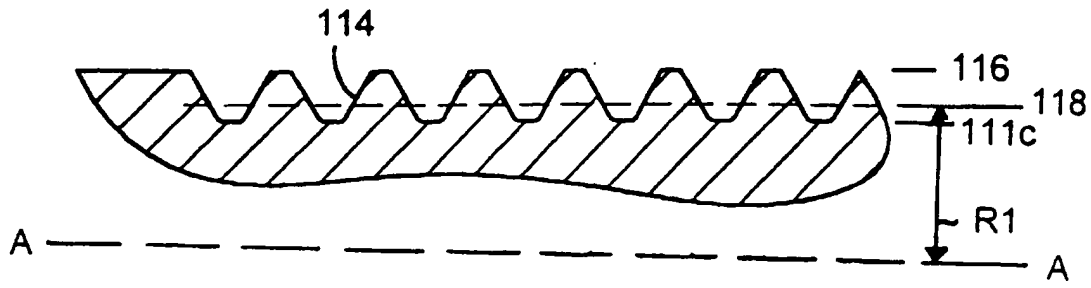

FIG. 12

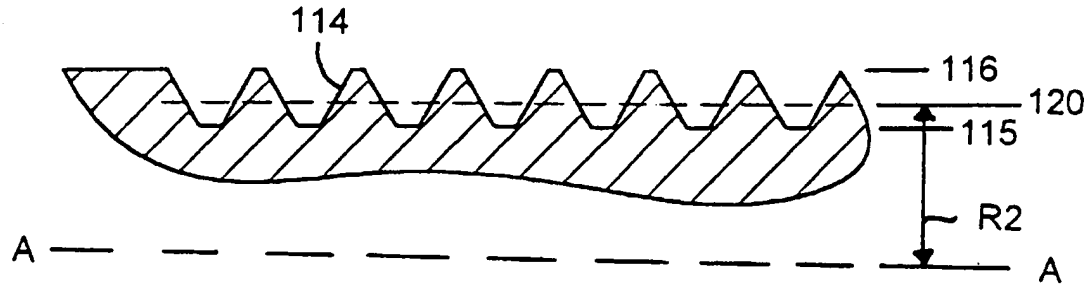

FIG. 13

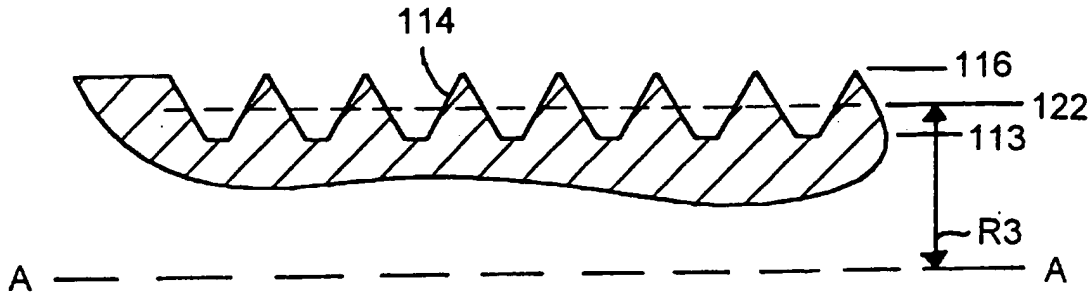

FIG. 14

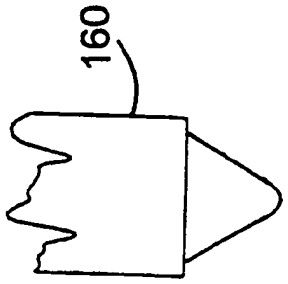

FIG. 17

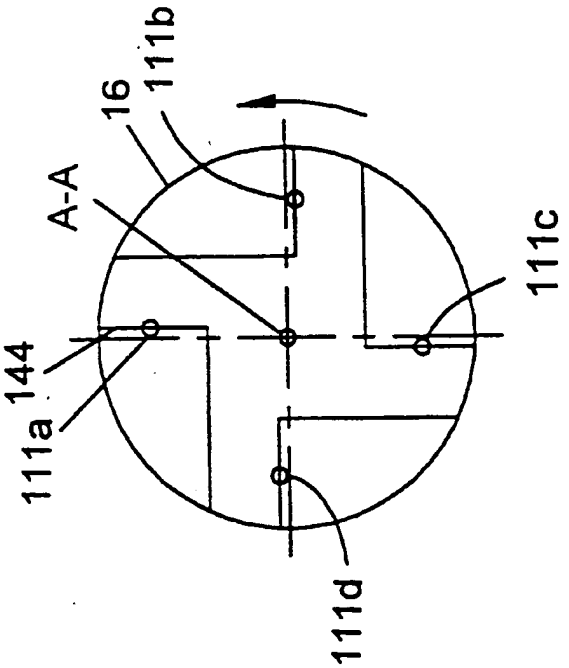

FIG. 16

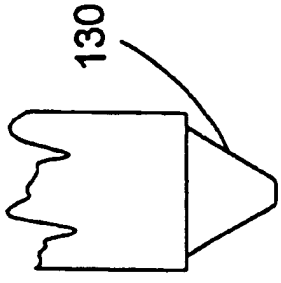

FIG. 15

REDUCED FRICTION SCREW-TYPE DENTAL IMPLANT

CROSS REFERENCES RELATED APPLICATIONS

This is a complete application claiming the benefit of now abandoned Provisional Patent Applications Serial No. 60/010,179; Filed Jan. 18, 1996 and Serial No. 60/011,034; Filed Feb. 2, 1996

FIELD OF THE INVENTION

This invention relates to improvements in screw-type dental implants and, in particular, to reducing the friction between the main body of such an implant and the side walls of a bore provided in living jawbone when the implant is screwed into that bore.

BACKGROUND OF THE INVENTION

Screw-type dental implants are widely used and have been known for a number of years. They are made in two general types. The first type is a self-tapping implant, in that it can be threaded into a pre-drilled bore in a jawbone without pre-tapping the bore. The second type is a non-self-tapping implant that requires pre-tapping of the bore. In either type, the implant has a generally cylindrical main body which bears one or more external screw threads on its outer surface. These external thread(s) engage corresponding internal thread(s) cut into the wall of the bore to provide initial stabilization of the implant in the bore.

A problem commonly encountered is the friction between the implant and the bone walls defining the bore. The friction is proportional to the penetration depth of the implant into the bone, the diameter of the bore, and the hardness of the bone at the site of the bore. The torque that must be applied to insert the implant into the bore is proportional to the friction. High torque puts strains on the implant, on the tools used to place the implant in the bore, and on the bone. Furthermore, in cases where high torque is required to insert the implant, there is a greater risk of damage to the implant, the tools, and the bone. Consequently, there is a continuing need to design a screw-type dental implant which minimizes the torque needed to install it into living jawbone.

SUMMARY OF THE INVENTION

In the design of screw-type dental implants as presently practiced, the main body of the implant is generally cylindrical. The thread peaks and thread roots (troughs) are each on the locus of a cylinder with each cylinder being concentric about the cylinder axis of the main body.

It is a primary object of this invention to provide an improved dental implant that reduces the torque required to install the implant into the bore in the jawbone and fix it in place in that bore.

Another object of the invention is to provide an improved screw-type dental implant that reduces the torque required to install the implant by reducing the friction between the implant and the sidewalls of the bore. A related object is to reduce the time and effort required to install the implant.

An additional object of the invention is to provide an improved screw-type dental implant that will resist forces tending to unscrew it from the bore after it has been installed.

Other objects and advantages of the invention will become apparent from the following description and the accompanying drawings.

In accordance with the present invention the foregoing objectives are realized by providing an improved screw-type dental implant comprising a generally cylindrical body having a threaded outer surface for securing the implant to the walls of a preformed hole in a jawbone. At least one dimensional characteristic of the body is varied with respect to its azimuthal position around the cylinder axis so as reduce the overall frictional contact between the implant body and the walls of the bore during installation of the implant. The variance in this dimensional characteristic also serves to resist turning of the body in the bore after the bone in the side walls of the bore has grown onto the implant body in the normal healing process. Examples of such a dimensional characteristic include:

a) the radius of the locus of the peaks of the threads;

b) the radius of the locus of the troughs of the threads;

c) thickness of the threads; and

d) angle between the faces of the threads.

An embodiment of the invention may employ these and other characteristics variably according to the invention, singly or in combination with one or more of the others. The variation employed can be cyclical or random around the cylinder axis. It can be synchronous or it can progress or regress with respect to the axis as its proceeds along the axis from one end of the body toward the other end.

Generally, the invention may provide an implant in which some portions of (for example) the peaks or troughs of the threads are on the original cylinder lacking the varied radius while other portions of the same characteristic are within that cylinder so that they make less or no contact with the walls of the hole. This design has two effects. First, by reducing the area of implant body that makes contact with the walls of the bore, the friction between the implant and the bone during installation of the implant is reduced. And second, after the bone has grown during healing to touch the implant body around the irregular (non-circular) portions thereof, the implant body resists turning in the bone more than would a typical implant having a cylindrical body lacking the radial-dimension variations of the invention.

Similar considerations apply to varying the thickness of the threads with respect to azimuthal position around the cylinder axis. One technique for varying the radius of the locus of the thread peaks is also effective to vary the thickness of the threads synchronously with variation in the radius, so that these two characteristics can be employed simultaneously with one manufacturing process step.

In an exemplary embodiment of the invention that is described in this specification, the main body is modified to a non-circular cross-sectional shape having four lobes equally spaced around the cylinder axis. The lobes are aligned parallel to the cylinder axis, and the implant has a tapered end section with four self-tapping cutting edges spaced equally around the cylinder axis substantially in line with the lobes. This embodiment is described in the accompanying drawings, in which:

FIG. **1** is an implant incorporating the present invention;

FIG. **2** is a helical section taken along line **2**—**2** in FIG. **1**;

FIG. **3** is a longitudinal half-section taken on line **3**—**3** in FIG. **2**;

FIG. **4** is a longitudinal half-section taken on line **4**—**4** in FIG. **2**;

FIG. **5** represents a thread-forming tool useful to make the implant;

FIG. **6** schematically illustrates a property of the invention; and

FIG. 7 is a graph illustrating the reduced torque accomplished due to the present invention.

FIG. 8 is another implant which may incorporate an alternative embodiment of the present invention;

FIG. 9 is partial view of an implant incorporating the present invention;

FIG. 10 illustrates three vertically-adjacent threads unrolled;

FIG. 11 is a helical section taken along line 11—11 in FIG. 8;

FIG. 12 is a longitudinal half-section taken along line 12—12 in FIG. 11;

FIG. 13 is a longitudinal half-section taken along line 13—13 in FIG. 11;

FIG. 14 is a longitudinal half-section taken along line 14—14 in FIG. 11;

FIG. 15 represents a thread-forming tool useful to make the implant;

FIG. 16 schematically illustrates a property of the invention; and

FIG. 17 is an alternative cutting tool for forming threads.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates an implant **10** which incorporates the present design. The implant **10** has a main body **12** with external threads **14**. A sectional line **2—2** is a helical section line in that it is taken along the trough between two adjacent threads **14**. This section is shown in FIG. **2**.

In FIG. **2**, the main body **12** of the implant **10** has a non-circular shape as seen transverse to the longitudinal axis A—A (FIG. **2**), with external threads **14** having peak diameters in a cylindrical locus **16**. The non-circular shape has four lobes **12***a*, **12***b*, **12***c* and **12***d* arrayed symmetrically around the axis A—A. The non-circular shape can be a variety of shapes including rhombic or rhomboidal. One of these lobes, **12***a*, defines the troughs of the threads **14** which are on the main body **12**, shown in FIG. **3**. Between the lobes are four equally-spaced dwell regions **12***w*, **12***x*, **12***y* and **12***z*, of the main body **12**. The mid-point of one of these dwell regions, falling on line **4—4** in FIG. **2**, defines the troughs of the threads **14** as shown in FIG. **4**. The troughs defined by dwell **12***w* in FIG. **4** are deeper than the troughs defined by lobe **12***a* in FIG. **3**. The peak diameters of the threads **14** on the main body **12** are the same in both FIGS. **3** and **4**. The threads **14** are cut deeper in the dwell region **12***w* illustrated in FIG. **4** than they are cut in the lobe region **12***a* illustrated in FIG. **3**, without the peak diameter changing in either location.

The threads **14** may be cut with a tool such as the tool **30** shown in FIG. **5**, which has a shape that can be pushed into the main body **12** as it is turned in a lathe according to a cyclical pattern to form the alternating lobes and dwell regions. When this tool **30** is pushed into the main body **12** far enough to form a dwell region, the threads **14** are made thinner in the region of the larger pitch diameter **18** as compared with the thread shape formed when the tool is pushed into a shallower depth to form a lobe. As a result, the pitch diameter **18** of the threads **14** shown in FIG. **3** is larger than the pitch diameter **20** of the deeper threads shown in FIG. **4**.

The illustrated dental implant **10** has a tapered end part **40** wherein both the peaks and the troughs of the threads **14***b* taper on respective substantially conical loci toward the extreme end **42** of the main body **12**. This tapered end part **40** is fitted with four self-tapping cutting means arrayed symmetrically around the axis A—A, of which only **144** is shown in FIG. **3**. As is apparent in FIG. **3**, each cutting means is aligned with one of the lobes **12***a–d*, respectively, and therefore with the larger pitch diameter. This relationship is schematically illustrated in FIG. **6**.

FIG. **7** illustrates the benefits derived from the present invention in graphical form. The dashed line (**1**) shows the torque of a 6.0 mm diameter implant which does not incorporate the present invention as it is screwed into a test fixture. The torque reaches nearly 60 Nxcm. The darker solid line (**2**) is a 6.0 mm diameter implant utilizing the present invention shown in FIGS. **1–6**. The peak torque is approximately 40 Nxcm, which is substantially less than dashed line (**1**). The thin solid line (**3**) is the torque required for a smaller 3.75 mm diameter implant that does not incorporate the design of the present invention. As can be seen, the peak torque for the 6.0 mm implant incorporating the present invention is similar to the torque requirement for the much smaller 3.75 mm implant. Furthermore, the rate at which the torque of darker line (**2**) increases is gradual making installation easier.

A further note concerning FIG. **7** is that the maximum torque for the machine screwing the implants into the test fixture was set at approximately 60 Nxcm. The 6.0 mm implant without the present invention, dashed line (**1**), could not be fully screwed into the test fixture with this limit on the torque. Consequently, the quick fall in dashed line (**1**) indicates the time at which the machine reached its torque limit. The fall in the darker solid line (**2**) indicates the point of full installation. Because the number of threads per inch on both 6.0 mm specimens was the same, the time at which both 6.0 mm specimens should have reached the desired full-installation point should have been the same since the revolutions per minute of the machine in each test were the same. Thus, because solid line (**2**) drops off about at twice the time as dashed line (**1**), the implant lacking the claimed invention was only capable of being inserted about half the desired installation depth into the test fixture.

FIG. **8** illustrates a typical implant **110'** which may incorporate an alternative embodiment of the present design. The implant **110'** has a main body **112'** with external threads **114'**. FIG. **9** illustrates the details of the alternative embodiment of the present invention on the threads **114** of the implant **110**. The top portion of the implant **110'** in FIG. **9** has a slightly different configuration than the top portion of the implant **110** in FIG. **8**. As with the previous embodiment of FIGS. **1–7**, the alternative embodiment of the present invention relates to the threads **114** and can be incorporated on any implant regardless of the configuration at its top. A sectional line **11—11** in FIG. **9** is a helical section line in that it is taken along the trough between two adjacent threads **114** as it spirals up the implant **110**. This section is shown in FIG. **11**.

In FIGS. **9** and **11**, the main body **112** of the implant **110** has a non-circular shape as seen transverse to the longitudinal axis A—A, with external threads **114** having major diameters in a cylindrical locus **116**. Four lobes **111** are arrayed symmetrically around the axis A—A with peak minor diameters **111***a*, **111***b*, **111***c*, and **111***d* following along locus **117**. Between the lobes **111** are four equally-spaced dwell regions **113** of the main body **112**. A drop region **115** is located between each peak minor diameter **111***a–111d* and each adjacent dwell region **113**. In the dwell region **113**, the distance "D" represents the spacing between the body **112** of the implant **110** and the surface of the bone tissue.

To assist in visualizing the present invention, FIG. **10** illustrates three vertically adjacent threads **114** unrolled from

the implant **110** and the troughs therebetween. The peak minor diameter **111***a* is shown with the drop regions **115** on either side. The dwell regions **113** are shown adjacent the drop regions **115**. The major diameter of the threads **114** lies on an edge at region **119***a* near the dwell regions **113**. Near the drop regions **115** and the peak minor diameters of the lobes **111**, the major diameter of the threads **114** lies on a surface **119***b*. The shape of surface **119***a* depends on the structure and depth of the drop regions **115** and the lobes **111**.

Angles X and Z in FIG. **11** represent the angular position over which drop regions **115** occur and are generally less than angle Y. In one embodiment, angles X and Z are the same value. In a preferred embodiment, angles X and Z are approximately 22.5° while angle Y is approximately 45° such that the summation of angles X, Y, and Z is substantially 90°. If only three lobes were employed, then the summation of angles X, Y and Z would be substantially 120° if the lobes were symmetrically spaced.

FIGS. **12**, **13**, and **14** illustrate the cross-section through lines **12**—**12**, **13**—**13**, and **14**—**14**, respectively, in FIG. **11**. The troughs defined by dwell regions **113** in FIG. **14** are deeper than the troughs defined by the lobe **111***c* in FIG. **12**. The troughs defined in the drop region **115** (FIG. **13**) have depth that is between the depths of the troughs of the lobe **111***c* and the dwell regions **113**. The peak diameters of the threads **114** along cylindrical locus **116** are the same in FIGS. **12**, **13**, and **14**. Thus, although the threads **114** are cut deeper in the dwell region **113** illustrated in FIG. **14** than they are cut in the region of the lobe **111***c* illustrated in FIG. **12** or the drop region **115** in FIG. **13**, the major diameter of the threads **114** does not change.

The threads **114** may be cut with a tool such as the tool **130** shown in FIG. **15**, which has a shape that can be pushed into the main body **112** as it is turned in a lathe according to a cyclical pattern to form the alternating lobes **111**, drop regions **115**, and dwell regions **113**. When this tool **130** is pushed into the main body **112** far enough to form a dwell region **113**, the threads **114** are made thinner near their major diameter than when the tool **130** is pushed in a short distance to form lobes **111**. As a result, the pitch diameters **118**, **120**, and **122** (and pitch radii) of the threads **114** shown in FIGS. **12**, **13**, and **14** become progressively smaller. Thus, pitch radius R1 (FIG. **12**) is larger than pitch radius R2 (FIG. **13**) which is larger than the pitch radius R3 (FIG. **14**).

The illustrated dental implant **110'** has a tapered end part **140** (FIG. **8**) wherein both the peaks and the troughs of the threads taper on respective substantially conical loci toward the extreme end **142** (FIG. **8**) of the main body **112'**. This tapered end part **140** is fitted with four self-tapping cutting means arrayed symmetrically around the axis A—A, of which one **44** is shown in FIG. **16**. As is apparent in FIG. **16** which illustrates schematically the relationship of the self-tapping cutting means and the lobes **111**, each cutting means is aligned with one of the lobes **111** and, therefore, with the larger pitch diameter. However, the lobes **111** can be misaligned from the self-tapping cutting means.

Various alternatives exist from the embodiment shown in FIGS. **8**–**16**. For example, the angles X, Y, and Z are shown having a summation that is substantially 90°. However, the summation of these angles, which dictates the angular position between adjacent lobes **111**, could be greater than or less than 90°. Thus, when viewing the implant **110** from the side, the lobes **111** may spiral in the same direction as the spiraling of the threads **114**, or in a direction that is opposite the spiraling of the threads **114**. As the angle representing the summation of angles X, Y, and Z increases or decreases from 90°, the more profound the spiraling of the lobes **111** will be.

Also, the major diameter of the threads **114** can be recessed as well in the dwell region **113**. This is accomplished by inserting the tool further toward the axis A—A of implant **110** shown in FIG. **14**. Thus, the cylindrical locus **116** (FIG. **11**) of the major diameter of the threads **114** would be altered to a non-cylindrical locus.

The tool used to develop the troughs between two vertically adjacent threads can also be rounded such as the rounded tool **160** in FIG. **17**. Thus, in FIGS. **12**–**14**, the area between two vertically adjacent threads would be defined by rounded sides of the threads instead of the flat sides of the threads **114** shown in FIGS. **12**–**14**. By rounding these sides between vertically adjacent threads the total surface area to which the bone tissue attaches is increased. Furthermore, the tool can also have offset cutting regions which cause the lobe to be cut at a different circumferential position near one side of a thread than at the opposing side of the vertically adjacent thread which forms the trough.

Additionally, the lobes **111** may only be located on portions of the implant **110** or the amount of relief, defined by distance "D" in the dwell region **113**, may be reduced. For example, when the implant **110** is used as a dental implant that is inserted into the jawbone, a portion of the implant **110** is located in the denser bone tissue of the cortical bone. Denser bone grows at a slower rate. Thus, because the bone tissue must grow toward the implant **110** for distance "D" in FIG. **11**, it may be appropriate to decrease distance "D" in the region adjacent to the cortical bone to reduce the time required for complete osseointegration in that dense bone region. It may even be desirable to have no relief ("D"=0) in the region of the denser cortical bone. However, in the less dense cancellous bone beyond the cortical bone, distance "D" may be an acceptable distance across which the cancellous bone may grow.

Furthermore, the implant **110** incorporating this invention may have its surface treated by acid etching and/or grit blasting. A novel way in which these surfaces are treated is illustrated in Ser. No. 08/351,214, filed Nov. 30, 1994, which is herein incorporated by reference in its entirety.

We claim:

1. An implant for implantation into bone tissue having an exterior surface comprising:

an elongated body having a distal end portion for being submerged in said bone tissue, a proximal end portion for being located near said exterior surface of said bone tissue, a central axis, and an outer surface, said elongated body having a non-circular cross-section transverse to said central axis, said non-circular cross-section including a plurality of lobes and a plurality of dwells, each of said plurality of dwells being circumferentially disposed between adjacent ones of said plurality of lobes; and

at least one thread making a plurality of turns around said elongated body and extending radially outward with respect to said central axis from said outer surface of said elongated body between said distal end portion and said proximal end portion.

2. The implant of claim **1** wherein said distal end portion of said elongated body includes a self-tapping screw-threaded region.

3. The implant of claim **2** wherein said self-tapping screw-threaded region includes multiple cutting surfaces, one of said plurality of lobes being axially aligned with one of said multiple cutting surfaces.

4. The implant of claim 2 wherein said at least one thread has a major diameter measured transverse said central axis, said major diameter being substantially constant between said proximal end portion and said self-tapping screw-threaded region.

5. The implant of claim 4 wherein said at least one thread has a crest defining said major diameter, said crest being flattened to present an axially extending surface in regions near said plurality of lobes and being an edge in regions near said plurality of dwells.

6. The implant of claim 2 wherein said plurality of lobes and said plurality of dwells decrease in their radial dimensions with respect to said central axis in said self-tapping screw-threaded region of said distal end portion.

7. The implant of claim 1 wherein said at least one thread has a major diameter measured transverse said central axis, said major diameter being substantially constant between said distal and proximal end portions.

8. The implant of claim 7 wherein said at least one thread has a crest defining said major diameter, said crest being flattened to present an axially extending surface in regions near said plurality of lobes and being an edge in regions near said plurality of dwells.

9. The implant of claim 7 wherein said at least one thread has a crest defining said major diameter, said crest being flattened to present an axially extending surface.

10. The implant of claim 1 wherein said at least one thread has a pitch radius measured from said central axis, said pitch radius being larger in regions near said plurality of lobes than in regions near said plurality of dwells.

11. The implant of claim 1 wherein said plurality of lobes and said plurality of dwells decrease in their radial dimensions with respect to said central axis at said distal end portion.

12. The implant of claim 1 wherein said outer surface of said elongated body is a root of said at least one thread, said root being a curved surface.

13. The implant of claim 1 wherein a central point of each of said plurality of dwells has a radius measured from said central axis, said radii having different values depending on the distance from said proximal end portion.

14. The implant of claim 13 wherein said radii of said plurality of dwells adjacent said proximal end portion are larger than said radii of said plurality of dwells on the remaining portions of said elongated body.

15. The implant of claim 14 wherein said radii of said plurality of dwells adjacent said proximal end portion are substantially the same as the radii of said plurality of lobes adjacent said proximal end portion.

16. The implant of claim 1 wherein at least one of said plurality of dwells has a central region that is substantially flat when viewed in said cross-section.

17. The implant of claim 1 wherein at least one of said plurality of dwells has a central region that is substantially curvilinear when viewed in said cross-section.

18. The implant of claim 17 wherein each of said plurality of dwells between said distal end portion and said proximal end portion are substantially curvilinear, said plurality of dwells being in a substantially cylindrical locus.

19. The implant of claim 18 wherein each of said plurality of lobes between said distal end portion and said proximal end portion project outwardly from said substantially cylindrical locus and have peaks, said peaks being on a second substantially cylindrical locus.

20. The implant of claim 19 wherein the number of each of said pluralities of lobes and dwells is four in said transverse direction, each of said four dwells and each of said four lobes extending an angular length of approximately 45° around said central axis.

21. The implant of claim 1 wherein said at least one thread has a variable major radius measured from said central axis in said cross-section, said major radius being larger in regions adjacent said lobes than in regions adjacent said dwells.

22. The implant of claim 1 wherein said adjacent ones of said plurality of lobes are circumferentially positioned from each other at a predetermined angle, said predetermined angle not being a multiple of 90° such that said plurality of lobes spiral along the axial length of said elongated body when viewed from the side.

23. The implant of claim 1 wherein the surfaces of said implant on said elongated body and said at least one thread undergo a treatment to enhance osseintegration.

24. The implant of claim 23 wherein said treatment includes grit-blasting.

25. The implant of claim 23 wherein said treatment includes acid-etching.

26. An implant for implantation into bone tissue having an exterior surface comprising:

an elongated body having a distal end portion for being submerged in said bone tissue, a proximal end portion for being located near said exterior surface of said bone tissue, a central axis, and an outer surface; and

a plurality of threads extending radially outward from said outer surface of said elongated body between said distal end portion and said proximal end portion, said plurality of threads having a substantially constant major radius and varying minor radius, said varying minor radius defining a plurality of lobes and a plurality of dwells, each of said plurality of dwells having a generally flat region when viewed axially with respect to said central axis and being circumferentially disposed between adjacent ones of said plurality of lobes, each of said plurality of lobes being substantially curvilinear when viewed axially with respect to said central axis, said plurality of dwells and lobes giving said elongated body a non-circular cross-section when taken transversely to said central axis; and

a self-tapping screw-threaded region within said distal end portion including a plurality of cutting surfaces, each of said cutting surfaces being substantially axially aligned with one of said lobes, each of said major and minor radii of said plurality of threads being smaller in said self-tapping screw-threaded region than in the remaining portions of said elongated body.

27. The implant of claim 26 wherein an average value of said minor radius through one rotation of said plurality of threads in regions outside of said self-tapping screw-threaded region have different values depending on the distance from said proximal end portion.

28. The implant of claim 27 wherein the average value of said minor diameter of said plurality of threads adjacent said proximal end portion is larger than the average value on the remaining portions of said elongated body.

29. The implant of claim 27 wherein the surfaces of said implant on said elongated body and said threads undergo a treatment to enhance osseintegration.

30. The implant of claim 29 wherein said treatment includes grit-blasting.

31. The implant of claim 29 wherein said treatment includes acid-etching.

32. An implant for implantation into bone tissue having an exterior surface comprising:

an elongated body having a distal end portion for being submerged in said bone tissue, a proximal end portion

for being located near said exterior surface of said bone tissue, a central axis, and an outer surface; and

a plurality of threads extending radially outward from said outer surface of said elongated body between said distal end portion and said proximal end portion, said plurality of threads having a substantially constant major radius and varying minor radius, said varying minor radius defining a plurality of lobes and a plurality of dwells, each of said plurality of dwells having a curvilinear region and being circumferentially disposed between adjacent ones of said plurality of lobes, each of said plurality of lobes being substantially curvilinear when viewed axially with respect to said central axis, said plurality of dwells and lobes giving said elongated body a non-circular cross-section when taken transversely to said central axis, each of said plurality of dwells between said proximal and distal end portions defining a generally cylindrical locus, each of said plurality of lobes projecting outwardly from said generally cylindrical locus; and

a self-tapping screw-threaded region within said distal end portion including a plurality of cutting surfaces, each of said cutting surfaces being substantially axially aligned with one of said lobes, each of said major and minor radii of said plurality of threads being smaller in said self-tapping screw-threaded region than in the remaining portions of said elongated body.

33. The implant of claim **32** wherein an average value of said minor radius through one rotation of said plurality of threads in regions outside of said self-tapping screw-threaded region differs depending on the distance from said proximal end portion.

34. The implant of claim **32** wherein the average value of said minor diameter of said plurality of threads adjacent said proximal end portion is larger than the average value on the remaining portions of said elongated body.

35. The implant of claim **32** wherein the surfaces of said implant on said elongated body and said threads undergo a treatment to enhance osseintegration.

36. The implant of claim **35** wherein said treatment includes grit-blasting.

37. The implant of claim **35** wherein said treatment includes acid-etching.

38. A method of installing an implant into bone tissue though the exterior surface of said bone tissue, comprising the steps of:

preparing a bore in said bone tissue through said exterior surface of said bone tissue;

tapping said bore;

providing an implant having an elongated body and at least one thread for engaging the bone tissue defining said bore, said elongated body having a distal end portion to be submerged in said bone tissue, a proximal end portion for being located near said exterior surface of said bone tissue, a central axis, and an outer surface, said elongated body having an non-circular shaped cross-section;

inserting said distal end of said implant into said bore; and

screwing said implant into said bore so that when viewed in cross-section only portions of said elongated body contact said bone tissue defining said bore so as to reduce the friction between said bone tissue and said implant.

39. The method of claim **38**, wherein said implant includes a self-tapping screw-threaded region within said distal end portion including a plurality of cutting surfaces, said steps of tapping said bore and screwing said implant into said bore are accomplished simultaneously.

40. The method of claim **38**, wherein said at least one thread has a varying minor radius defining a plurality of lobes and a plurality of dwells, each of said plurality of dwells being disposed between adjacent ones of said plurality of lobes, said plurality of lobes being said bone-contacting portions of said implant.

41. The method of claim **38**, wherein said at least one thread has a crest defining a non-constant major radius, only portions of said crest contacting said bone tissue.

42. A method of securing an implant in bone tissue, said implant being installed though the exterior surface of said bone tissue, comprising the steps of:

preparing a bore in said bone tissue through said exterior surface of said bone tissue;

tapping said bore;

providing an implant having an elongated body and at least one thread for engaging the bone tissue defining said bore, said at least one thread making a plurality of turns around said elongated body, said elongated body having a distal end portion to be submerged in said bone tissue, a proximal end portion for being located near said exterior surface of said bone tissue, a central axis, and an outer surface, said elongated body having regions for receiving said bone tissue residing entirely between adjacent turns of said at least one thread, said regions extending inwardly toward said central axis thereby giving said elongated body a non-circular cross-section;

installing said implant into said bore; and

allowing said bone tissue to grow into said regions between adjacent turns of said at least one thread.

43. The method of claim **42** wherein the surfaces of said implant on said elongated body and said threads undergo a treatment to enhance osseintegration.

44. The method of claim **43** wherein said treatment includes grit-blasting.

45. The method of claim **43** wherein said treatment includes acid-etching.

* * * * *

US005591029A

United States Patent [19]

Zuest

[11] Patent Number: 5,591,029

[45] Date of Patent: Jan. 7, 1997

[54] **DENTAL IMPLANT SYSTEM**

[75] Inventor: **Max Zuest**, San Diego, Calif.

[73] Assignee: **Zest Anchors, Inc.**, Escondido, Calif.

[21] Appl. No.: **102,353**

[22] Filed: **Aug. 5, 1993**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 861,183, Mar. 31, 1992, abandoned, which is a continuation of Ser. No. 751,661, Aug. 22, 1991, Pat. No. 5,254,005, which is a continuation of Ser. No. 436,432, Nov. 14, 1989, abandoned.

[51] **Int. Cl.**[6] **A61C 8/00**

[52] **U.S. Cl.** **433/173**; 433/174

[58] **Field of Search** 433/172, 173, 433/174

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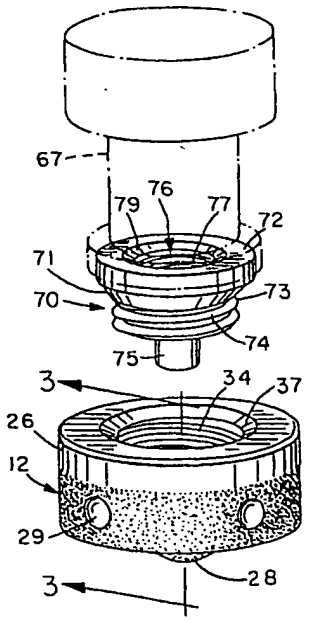
Primary Examiner—Cary E. O'Connor

Attorney, Agent, or Firm—Brown, Martin, Haller & McClain

[57] **ABSTRACT**

A dental implant assembly is provided, as well as a system and method for exposing an embedded implant after osseointegration has taken place. The implant assembly comprises an implant member for embedding in the jaw and a rest factor member for securing to the implant member, the rest factor member having an upper rest surface just above the tissue level for opposing an overlying portion of a prosthesis anchored elsewhere in the jaw to form a non-retentive rest or support for accepting down pressure from the prosthesis. The implant member is relatively short and can be installed in distal jaw regions without interference with the mandibular nerve. A bore is cut out in the jaw for receiving the implant, inserting the implant and an attached healing screw in the implant. The implant site is closed and osseointegration takes place over an extended period. Subsequently, the implant site is uncovered, the healing screw is removed, and the rest factor member is secured in the implant.

45 Claims, 6 Drawing Sheets



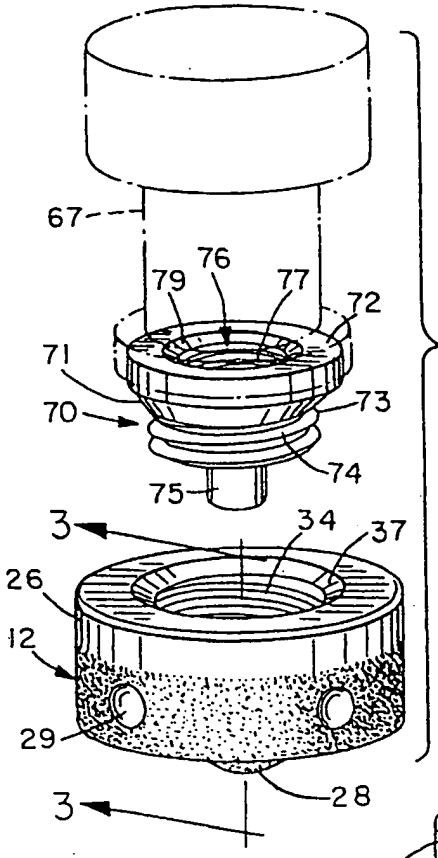


FIG. 1

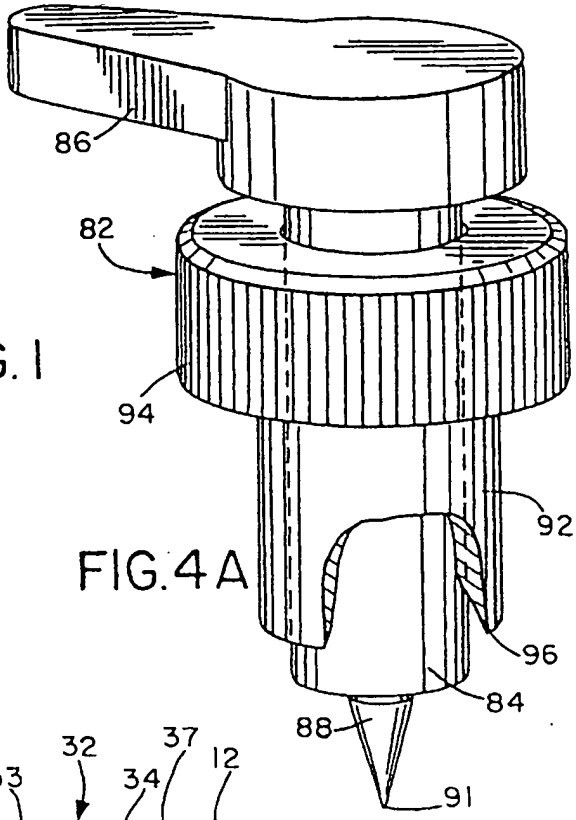


FIG. 4A

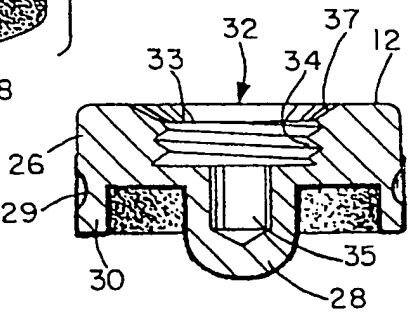


FIG. 3

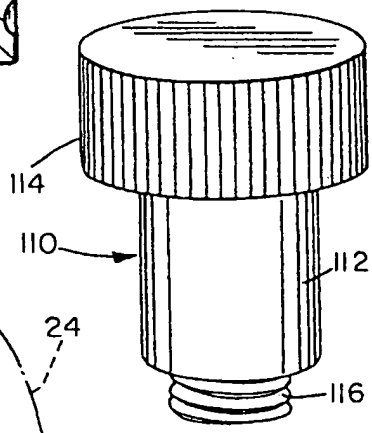


FIG. 4B

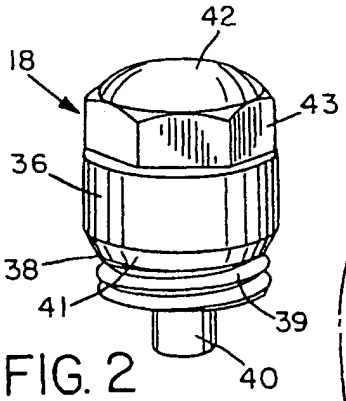


FIG. 2

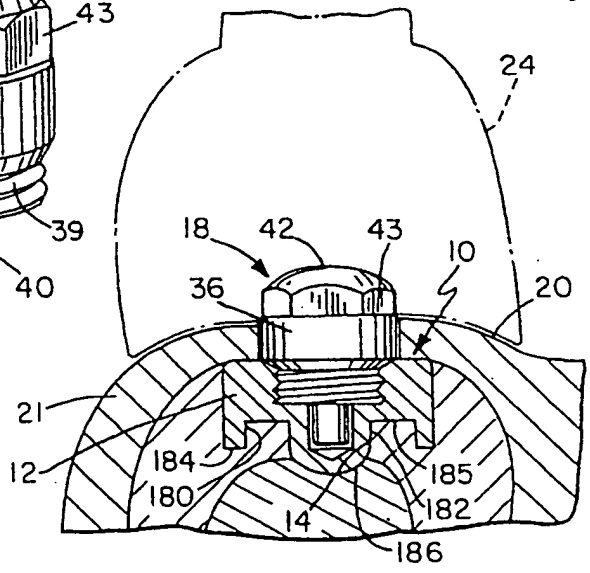


FIG. 5

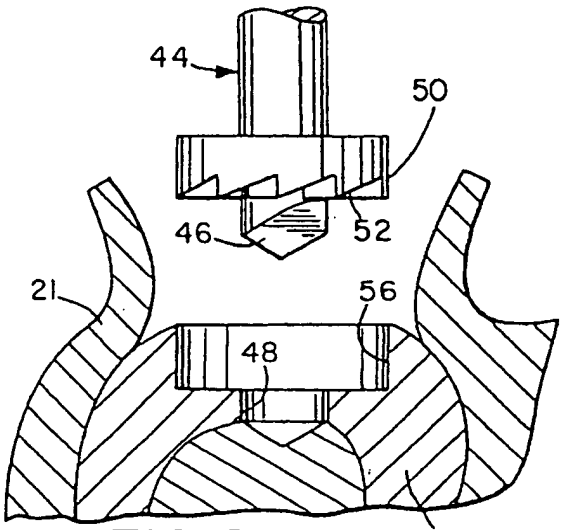


FIG. 6

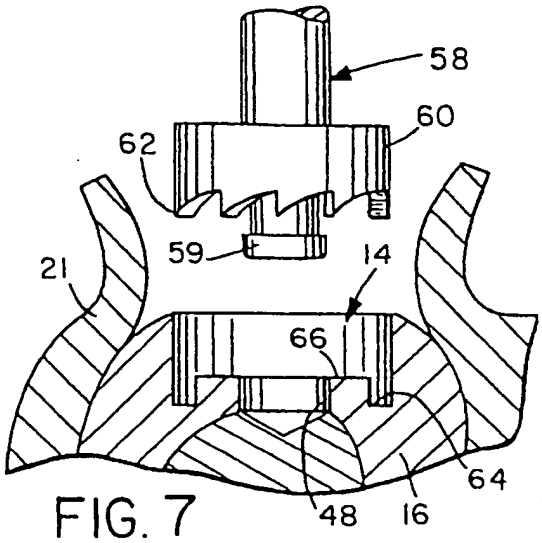


FIG. 7

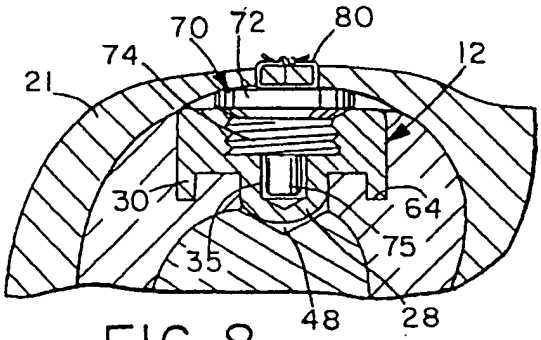


FIG. 8

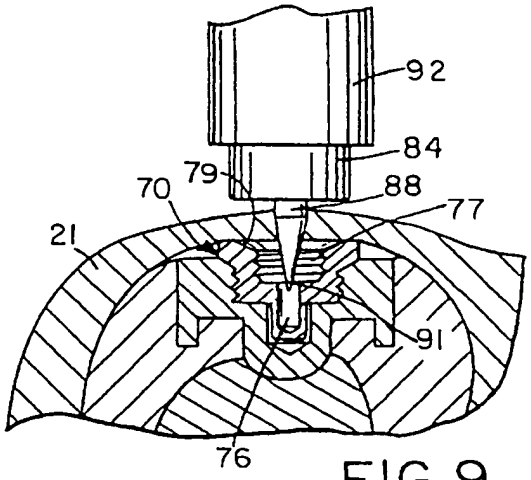


FIG. 9

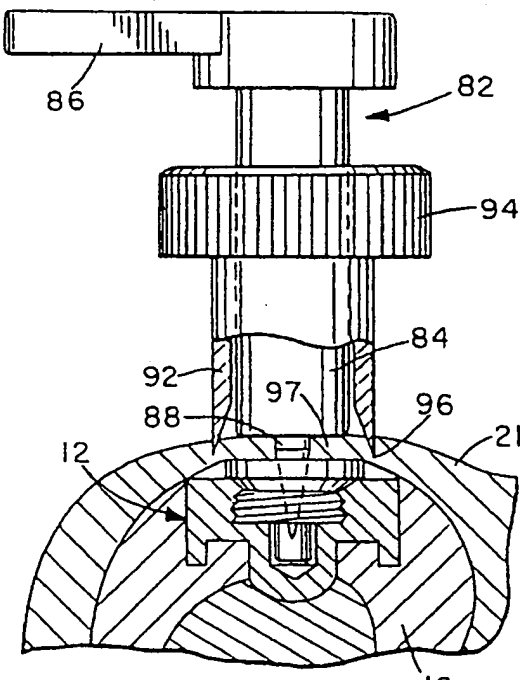


FIG. 10

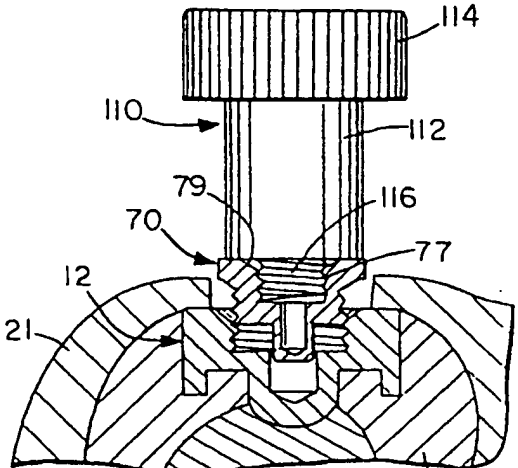


FIG. 11

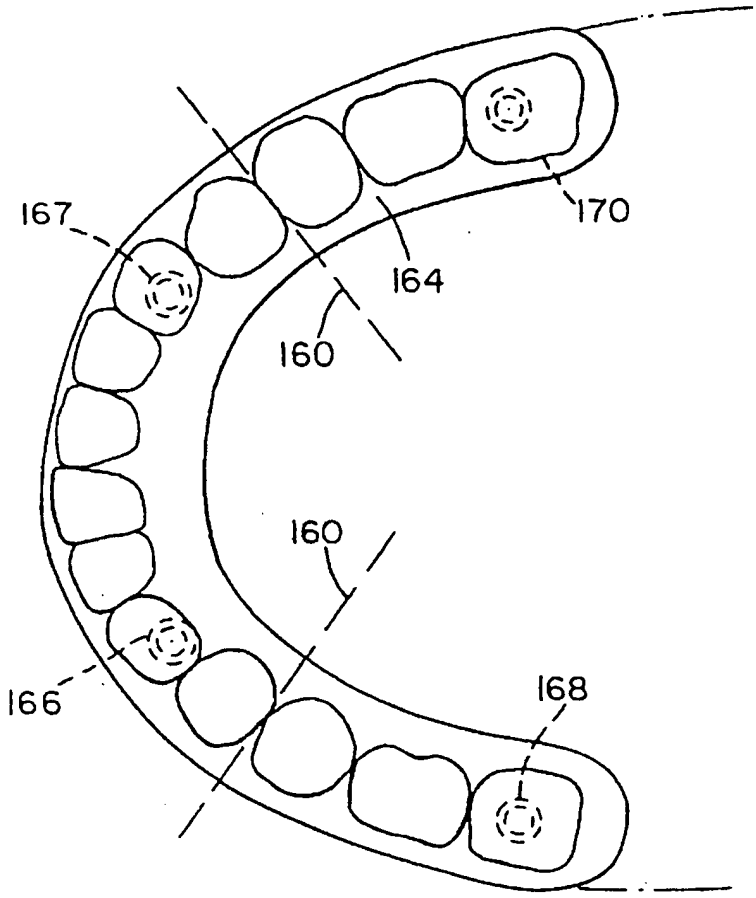

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FIG. 12

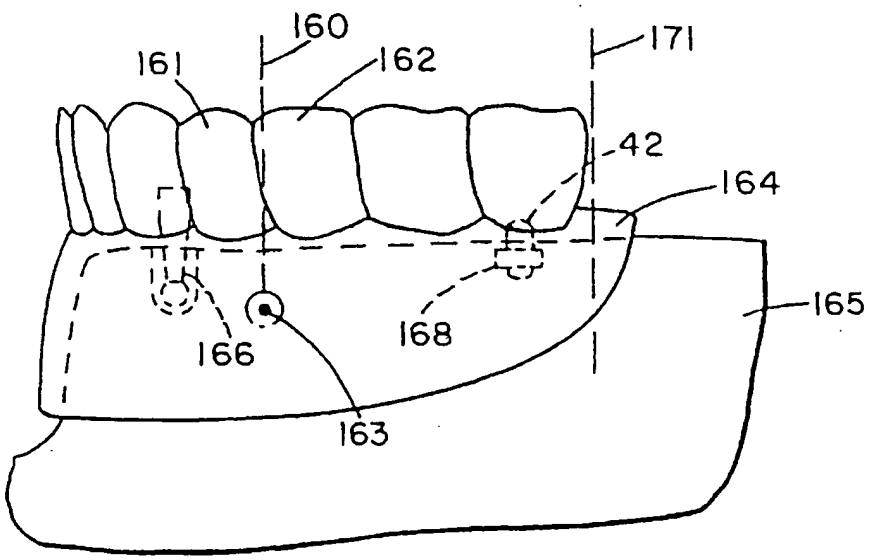
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FIG. 13

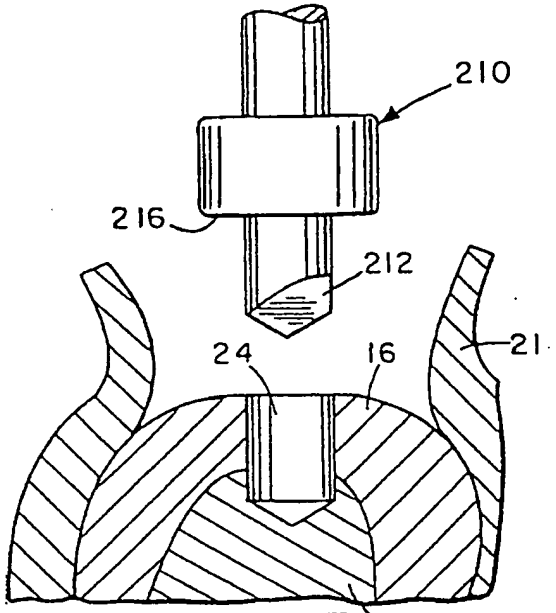


FIG. 15

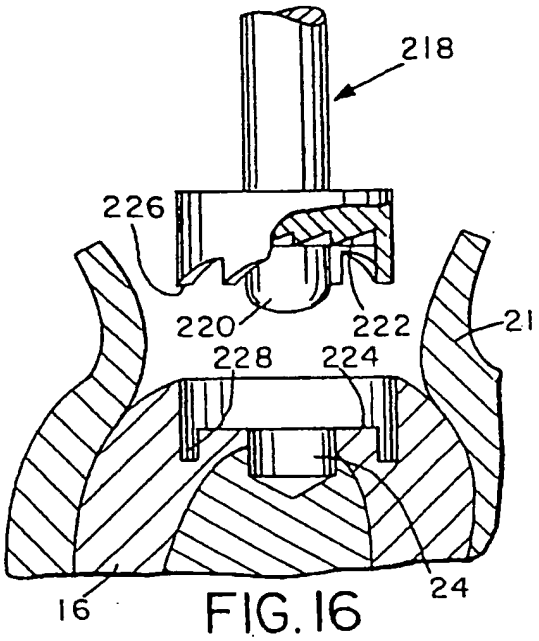


FIG. 16

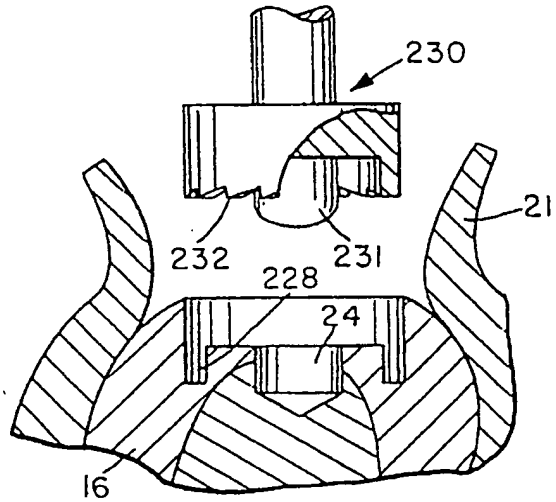


FIG. 17

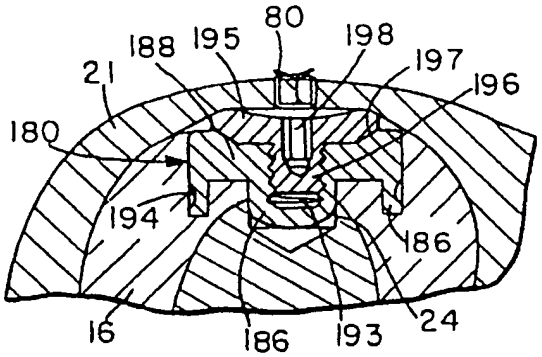
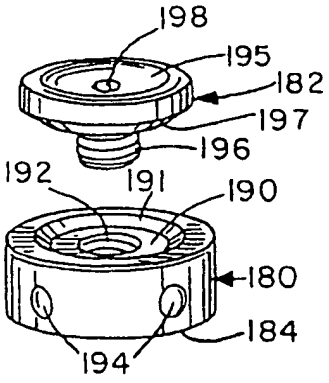


FIG. 18

FIG. 14



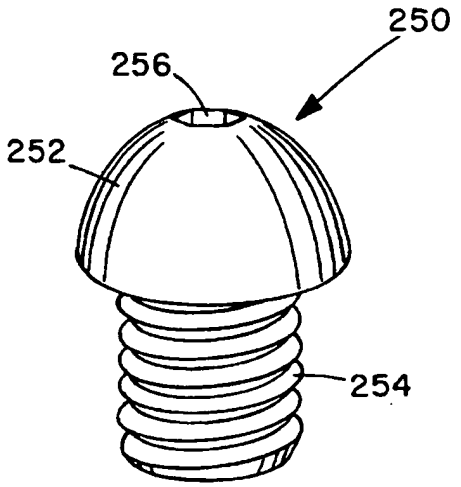


FIG. 19

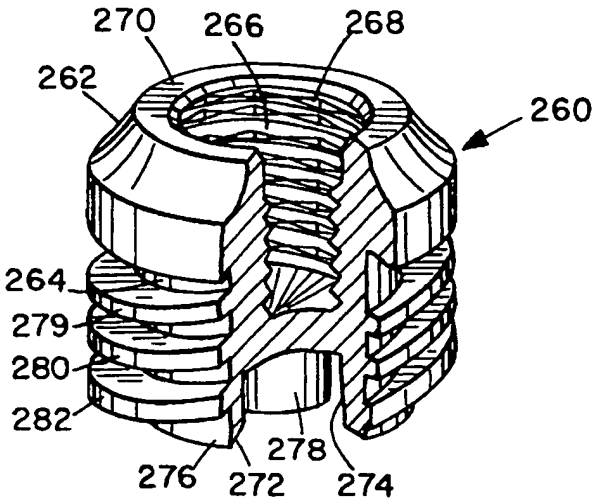


FIG. 20

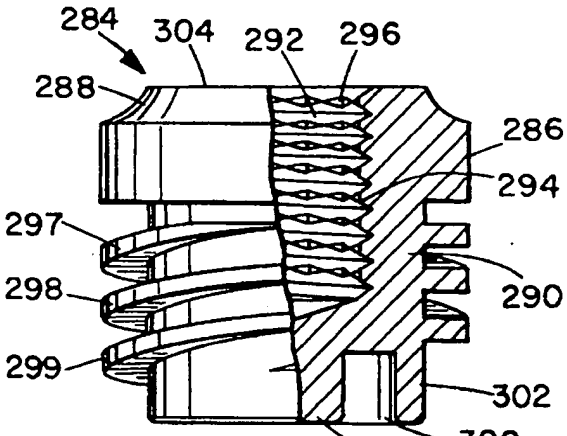


FIG. 21

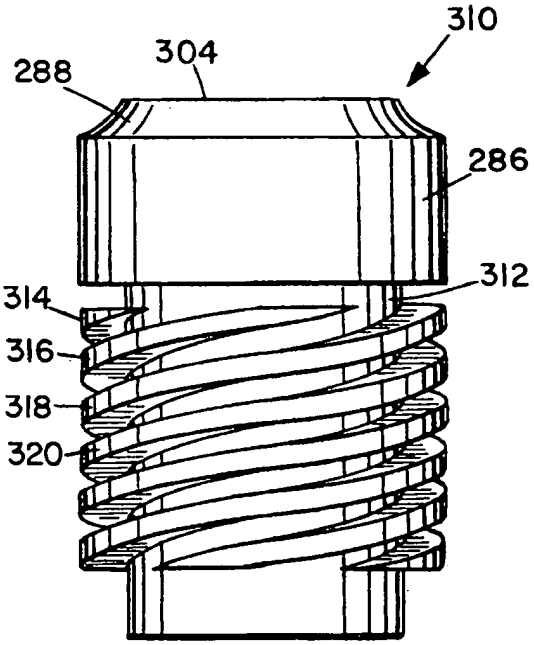


FIG. 22

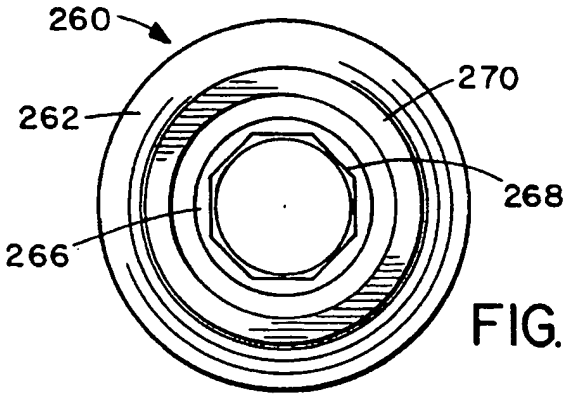


FIG. 23

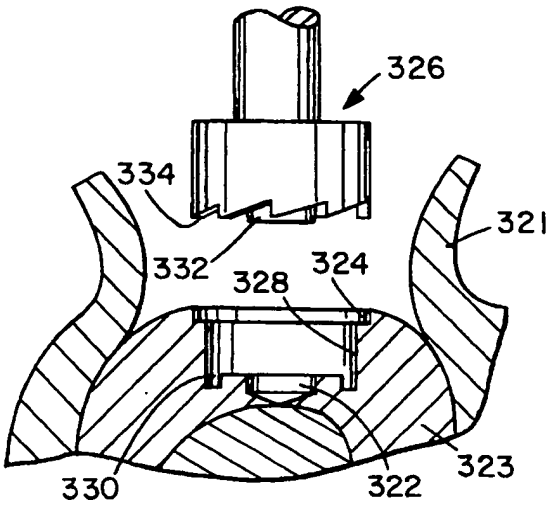


FIG. 24

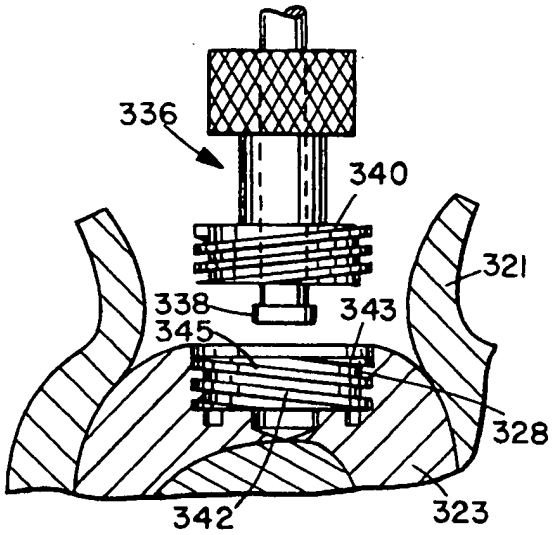


FIG. 25

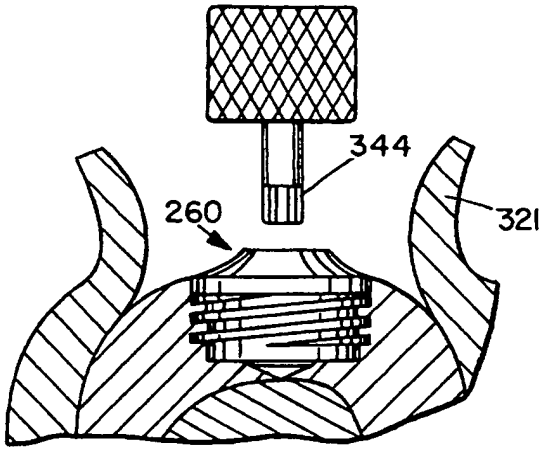


FIG. 26

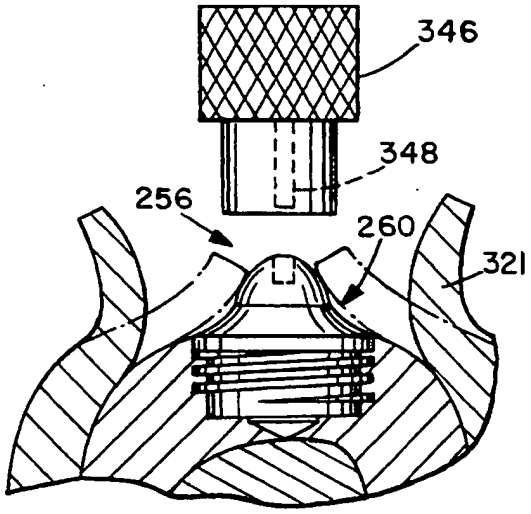


FIG. 27

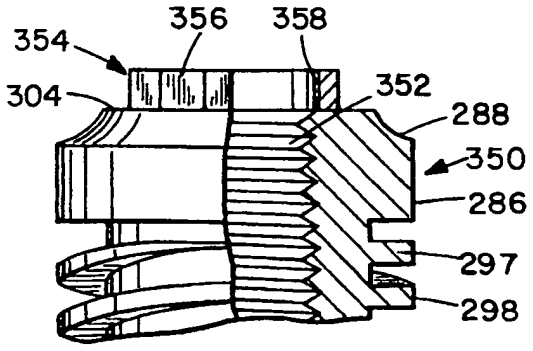


FIG. 28

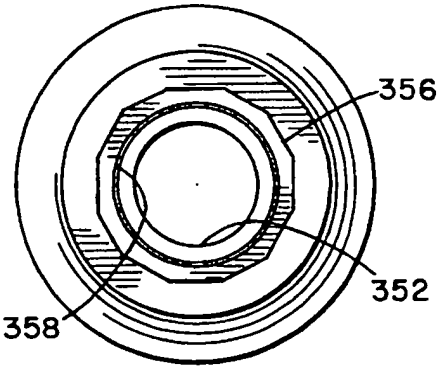


FIG. 29

DENTAL IMPLANT SYSTEM

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a Continuation-In-Part of application Ser. No. 07/861,183 filed Mar. 31, 1992, abandoned, which was a Continuation of application Ser. No. 07/751,661 filed Aug. 22, 1991, now U.S. Pat. No. 5,254,005, which was a Continuation of application Ser. No. 07/436,432 filed Nov. 14, 1989 (now abandoned).

BACKGROUND OF THE INVENTION

The present invention relates to a dental implant system.

Dental implants are embedded in the jaw bone and serve to anchor one or more artificial teeth or dentures. Most implant systems involve a relatively long implant cylinder which is placed into a custom bored hole in the jawbone, then left for several months to allow healing and bone integration. Then the implant must be exposed for attachment of a dental prosthetic appliance such as a crown, denture, partial denture or bridge. This generally involves the dentist cutting out a flap of tissue which is peeled back to expose the implant, and secured by sutures after installing the prosthesis. This results in a relatively large area of trauma with a certain degree of pain to the patient and risk of post-operative infection.

Another problem with conventional implants is their length, which makes them difficult to implant in the distal jaw region, where there is insufficient depth to enable their insertion without interference with the mandibular nerve, without the assistance of a dental surgeon to locate the precise position of the nerve and ensure that the implant does not interfere with it. A shorter cylindrical implant would not normally be suitable since it would provide insufficient "hold" and would likely become loosened with time if anchored to a denture or bridge. Also, side to side forces on the implant lead to bone erosion and trauma. Thus, dentures or bridges are often not anchored at the rear of the jaw. However, this has the disadvantage that trauma to the tissue and underlying bone beneath the denture occurs as a result of the denture repeatedly impacting the bone, particularly with long dentures which will tend to tilt or rotate about their attachment or anchor points during chewing or other jaw motions. This biting pressure can result in bone erosion or resorption down to the level of the nerve.

SUMMARY OF THE INVENTION

It is an object of this invention to provide an improved dental implant system and method which is less likely to cause significant tissue trauma and which reduces bone erosion as a result of denture wear.

It is a further object of this invention to provide an improved system and method for exposing an implant site after osseointegration has taken place.

According to a first aspect of the present invention, a dental implant assembly is provided which comprises a first, implant member for implanting in the distal region of the jaw bone, and a second member or rest factor for attachment to the implant member. The two members have cooperating releasable securing devices for releasably securing them together, preferably comprising a screw threaded bore in the implant member and a corresponding threaded portion on the rest factor member. The rest factor member projects up to just above the level of the tissue overlying the jaw bone and has an upper surface opposing an overlying portion of a prosthesis anchored elsewhere in the jaw to form a rest for the prosthesis which accepts down pressure only, and which acts as a support to prevent or restrict bone erosion. The implant member has a selected height less than the depth of the mandibular nerve at the implant site, so that it can be embedded in the bone without risk of interference with the nerve. At the same time, the implant member is as wide as possible, and preferably has the maximum diameter possible according to the width of the patient's alveolar ridge at the implant site. The implant member diameter is preferably selected to be 1 mm less than the available alveolar ridge or bone width at the implant site. Implant members in a range of different heights and diameters are preferably provided to meet the requirements of a range of patients. Preferably, implant members with heights of 2 mm, 4.5 mm, 7 mm and 10 mm are provided, to allow for patients whose jawbone is already eroded to some extent. Implant members with diameters ranging from about 4 mm to 6 mm may be provided.

Since the implant member is of relatively large diameter, it has a relatively large surface area resisting downward forces. In a preferred embodiment of the invention, the implant member has a generally cylindrical body with an upper end portion and downwardly depending stem portion which engages in a corresponding recess drilled out in the bone. Preferably, at least part of the stem portion at the lower end of the implant member has an annular recess forming an outer rim and central boss. This engages a corresponding annular recess drilled out in the bone to resist sideways movement of the implant. This will resist sideways movement of the implant during osseointegration, and also provides additional depth for securing the rest factor to the implant member. A bore of corresponding shape to the undersurface of the implant member is drilled out in the jawbone at the implant site, so that when the implant member is positioned in the bore, the peripheral rim will provide stabilization of the member against lateral movement during the osseointegration period. The shape of the undersurface of the implant provides a large area of bone to implant contact for osseointegration, and significant resistance to both lateral and downward forces both during and after the osseointegration period. Preferably, at least two separate or double lead threads are provided, and triple or quadruple threads may be provided for added retention. Bone grows into the gaps between threads.

The outer surface of the stem portion of the implant preferably has threads to provide additional surface area for bone attachment. Bone grows into the area above and below the threads to resist loosening of the implant.

Since the rest factor is not anchored to the prosthesis, the risk of jaw bone erosion or damage as a result of upward forces is reduced. However, the rest factor does accept down pressure as a result of biting pressure of the denture, and will thus reduce the risk of trauma to the tissue and jawbone erosion as a result of pressure. The localized contact between the rest factor and the underlying bone via the implant member reduces or substantially eliminates pressure trauma on the entire bone.

If desired, the upper surface of the rest factor and the opposing portion of the prosthesis may be provided with opposing, non-retentive mating formations, such as opposing slightly convex and concave formations, for guiding the prosthesis against the rest factor. However, these formations do not provide any upwards retention of the prosthesis. A series of such rest factors may be provided at appropriate locations in the jaw where maximum down pressure from a denture is encountered, considerably reducing the discom-

fort of denture use and reducing the risk of tissue and jawbone damage as would result from conventionally anchored dentures.

The rest factor may be preformed with a suitable rest surface in incremental heights, in which case the procedure after removing the healing screw comprises selecting an appropriate height rest factor and securing the selected rest factor in the implant member.

The implant member may be relatively short with a relatively large diameter, so that it can be anchored securely in the jawbone without needing a deep bore to be drilled out. The implant member is provided in several heights. The shortest of the implants will be shorter and wider than conventional cylindrical implants, and thus can be used at the back or posterior mandible of the jaw where the nerve position prevents or restricts the use of long implants. This implant is particularly suitable for positioning a rest factor in the second molar area in conjunction with implant dentistry where cantilevered bridges or anterior implants need support or in other places where a rest factor is needed in dentistry. The implant requires less bone to be drilled out than conventional cylindrical implants, reducing or minimizing bone loss, and is able to accept hundreds of pounds of down pressure from an overlying denture or prosthesis.

After bone integration, the implant can be recovered by piercing the tissue overlying a healing screw secured to the implant with a pointed end of a locating guide tool, probing the implant site with the pointed end until it engages a hole in the top of the healing screw, inserting the pointed end into the hole, utilizing a tissue punch centered on the guide tool to cut out a plug of tissue directly over the implant, and subsequently removing the healing screw.

Thus, the locating tool and tissue punch can be removed together from the implant site, carrying with them the tissue plug to expose the healing screw for removal with a separate tool. The implant is then exposed for secondary healing or restoration procedures while a minimum amount of tissue has been disturbed and little or no suturing is required. This considerably reduces the trauma, secondary tissue healing, discomfort to the patient, and risk of infection.

The implant member provides osseointegration with good resistance to loosening forces as a result of chewing. It may alternatively be used to secure other dental devices such as an implant denture anchor or an implant magnet abutment.

An implant locating and exposing tool may be used to recover the implant. The tool comprises an elongate shaft having a head at one end and a locating probe at the opposite end having a sharp end for probing the tissue over an implant site to locate a central hole in the top of a healing screw, and a cutter member mounted on the elongate member with its cutting face facing in the same direction as the locating probe, the cutter member being movable along the elongate shaft to cut out a plug of tissue overlying a healing screw.

Thus, the healing screw can be located and the overlying tissue removed in one step, without having to cut out a relatively large flap of tissue.

The healing screw may be provided with a concave upper surface so that the locating probe will be guided towards the central opening.

The implant system and method described above provides a rest surface for an overlying cantilevered bridge or denture which is anchored elsewhere in the jaw, on which the denture can rest and which accepts down pressure from the denture, reducing tissue trauma. Rest surfaces may be provided wherever needed, in conjunction with the conventional implants and anchors used for securing the denture or prosthesis in the jaw. The improved implant recovery tool and method produces minimal trauma when exposing a previously embedded implant for subsequent connection to either a rest factor or to a conventional anchor or magnet abutment.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be better understood from the following detailed description of a preferred embodiment of the invention, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts, and in which:

FIG. **1** is a perspective view of the separated implant and healing screw components of an implant assembly according to a preferred embodiment of the invention;

FIG. **2** is a perspective view of a rest factor of the implant assembly;

FIG. **3** is a sectional view of the implant taken on line **3**—**3** of FIG. **1**;

FIG. **4A** is a perspective view of a preferred embodiment of the implant locating tool according to another aspect of the invention;

FIG. **4B** is a perspective view of a healing screw removal tool;

FIG. **5** is a sectional view through a typical jawbone with a finished implant in place and a rest factor inserted;

FIG. **6** is a jawbone section illustrating the initial drilling set up for an implant;

FIG. **7** is a similar view illustrating the final counterboring operation for an implant;

FIG. **8** is a similar view with an implant and healing screw in place and enclosed under tissue for the osseointegration period;

FIG. **9** illustrates the locating of the integrated implant under the issue;

FIG. **10** illustrates the cutting out of a tissue plug overlying the healing screw;

FIG. **11** illustrates the removal of the healing screw;

FIG. **12** illustrates the lower half of a patient's jaw with a full denture anchored in place and seated on rest factors in posterior areas on both sides;

FIG. **13** is a side view of the denture arrangement of FIG. **12**;

FIG. **14** is a perspective view of the separated implant and healing screw components of an implant assembly according to a second embodiment of the invention;

FIG. **15** is a jawbone section illustrating the initial drilling set up for the implant of FIG. **14**;

FIG. **16** is a similar view to FIG. **15** illustrating the next step in the drilling procedure;

FIG. **17** is a similar view illustrating the finishing step in the boring operation;

FIG. **18** is a similar view illustrating the implant and healing screw in place and enclosed under tissue for the osseointegration period;

FIG. **19** is a perspective view of a rest factor according to another embodiment of the invention;

FIG. **20** is a perspective view, partially cut away, of one example of an implant for the rest factor of FIG. **19**;

FIG. **21** is a side elevation view, partially cut away, of another implant with triple retaining threads;

FIG. 22 is a side elevation view of a further implant with quadruple threads;

FIG. 23 is a top plan view of FIG. 20;

FIG. 24 is a view similar to FIG. 7, showing the addition of a shallow counter-bore;

FIG. 25 is a similar view showing the cutting of threads to receive an implant;

FIG. 26 is a similar view showing insertion of the implant;

FIG. 27 is a similar view showing attachment of the rest factor;

FIG. 28 is a side elevation view, partially cut away, of another modified implant having an alternative wrench element; and

FIG. 29 is a top plan view of the implant of FIG. 28.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1—3 and 5 of the drawings illustrate an implant assembly **10** according to a preferred embodiment of the present invention, as well as a preferred method of installing the assembly in the jaw. As best illustrated in FIG. 5, the implant assembly **10** basically comprises an implant **12** for insertion into a suitably prepared bore **14** in the jawbone **16**, where it is secured in place by osseointegration as is known in the field of implant dentistry, and an extension member or rest factor **18** secured to the implant **12** and extending up to slightly above the level **20** of the tissue or gum **21** to form a rest surface **22** for an overlying denture or bridge **24** which is anchored elsewhere in the jaw.

As best illustrated in FIGS. 1 and 3, implant **12** comprises a thin, annular member **26** having a central spigot or downward extension **28** projecting from one of its faces and an annular peripheral rim **30** projecting from the same face. A central bore **32** extends from the opposite face into the spigot **28**, as illustrated in FIG. 4. The bore **32** has a larger diameter upper portion **33** having internal screw threads **34** extending along its length with a taper **37** at its upper end for added strength to hold the threaded engagement. The lower end of bore **32** comprises a smaller diameter lower portion **35** extending into spigot **28** for centering parts mating with implant **12** and preventing cross-threading of the threaded engagement. The implant will be of metal or any suitably rigid material as is normally used for dental implants, for example surgical titanium alloy. The implant may have spaced, short grooves or indents **29** on its outer surface for resisting rotation. These are preferably of the order of 1 mm in length.

Also illustrated in FIG. 1 is a healing screw **70** for insertion in the implant member during the osseointegration process. Healing screw **70** has a relatively short head portion **72** and downwardly depending shaft portion **73** for engagement in the bore **32** of implant **12**. Portion **73** has a screw threaded larger diameter upper part **74** for threaded engagement in bore portion **33**, the upper part **74** having a taper **71** at its upper end matching the taper **37** at the upper end of the implant bore **32** for support and seating of the screw **70** in bore **32**. The lower end of portion **73** comprises a smaller diameter, cylindrical lower part **75** for fitting into lower portion **35**. The upper end face of the head portion has a central, tool receiving bore **76** for receiving the end of a suitable tool for inserting the arrangement in the bore in the jawbone, and for subsequently receiving the end of a locating or removing tool as will be explained in more detail below. If desired, the upper end face of screw **70** may have a concave or dish-shaped depression **79** surrounding bore **76**. The bore corresponding to bore **76** is illustrated in FIG. **11** and has a screw threaded upper portion **77** and a downwardly depending cylindrical centering extension **76** corresponding to extension **75** in FIG. **1**. The threads in upper portion **77** are of opposite hand to those of screw threaded portion **74**. In the embodiment illustrated in the drawings, portion **74** has a right hand thread while portion **77** has a left hand thread. The healing screw may be provided in a range of sizes, but in each case the height of the head portion is of the order of 1 mm or less.

The extension or rest factor member **18** as it appears prior to installation in the jaw is illustrated in FIG. **2**. The member comprises a generally cylindrical boss **36** having a projecting shaft **38** at one end dimensioned for mating engagement in the bore **32** of implant **12**. Shaft **38** has an upper, larger diameter portion **39** having external screw threads for threaded engagement with the internal screw threads **34** in the upper part **33** of bore **32**, and a lower, smaller diameter cylindrical extension **40** for fitting into the lower part **35** of bore **32**, as illustrated in FIG. **11**. The upper end of shaft **38** has a taper **41** matching the taper **37** at the upper end of the implant bore **32**. Member **18** has a curved, slightly convex rest or support surface **42** at its upper end, and an external hex formation **43** for securing it to a suitable tool for insertion into the implant. The member **18** will also be of a suitable dental material such as titanium alloy.

Member **18** may alternatively be formed with a concave support surface (not illustrated), or with any suitably shaped upper rest or support surface. Member **18** will be made in a range of heights to allow the dentist to select the appropriate size rest factor for a particular patient's tissue level. The rest factor is selected to project only to a distance of the order of ½ to 1 mm above the tissue level when installed in the jaw, and is preferably kept as low as possible so that it acts to accept biting pressures but will not interfere with normal jaw motions.

The implant assembly with the rest surface **42** is used to form a rest or support surface in implant dentistry for a prosthesis anchored elsewhere in the jaw, for example, as illustrated in FIGS. **12** and **13**. The implant assembly is designed to be relatively short or thin so that it can be installed in distal jaw regions to the rear of line **160** in FIGS. **12** and **13**, which extends between the first and second bicuspids **161** and **162** and corresponds to the approximate location where the mandibular nerve **163** exits the jawbone. The mandibular nerve extends through the jawbone to the rear of the first bicuspid, making the installation of long implants in this region difficult or impossible without the assistance of a dental surgeon. Thus, unsecured dentures are common, resulting in bone erosion from biting impacts. This rest factor assembly avoids or reduces such problems. The implant has a relatively large diameter as compared to its height, providing good implant to bone contact and integration, while having only a short penetration into the jawbone. In the preferred embodiment illustrated, the penetration into jawbone is only between 2 to 4.5 mm, depending on the patient's bone depth, and there is thus no risk of interference with the mandibular nerve.

FIGS. **12** and **13** illustrate the assembly implanted in the jaw for cooperation with an overlying denture anchored elsewhere. In FIGS. **12** and **13**, a full denture or prosthesis **164** is illustrated, secured to a patient's lower jaw **165** via a pair of anchors **166**, **167** mounted in the anterior regions of the patient's jaw, and seated on implanted rest factors **168**, **170** in the posterior or distal jaw region below the former second molar at each end of the denture. In practice, the rest

factor assembly may be installed anywhere between the region corresponding to the former second molar (line **171**) and the first bicuspid (line **160**). The area to the rear of the line **171** has too many muscles for insertion of an implant. As illustrated in FIG. **13**, the rest factors may be provided or preformed with a slightly convex or ball-shaped head **42** which projects from around ½ to 1 mm above the tissue level, although support surfaces of a different shape may be provided. The prosthesis or denture is preferably provided with a corresponding concave surface or depression for seating on the opposing rest factors or surfaces **168** and **170**.

Most typical denture anchors allow a limited degree of pivoting or side-to-side motions of the denture with jaw motions so as to reduce stress in the jaw bone areas to which the denture is positively anchored. With relatively long partial or full dentures which extend into the posterior jaw regions, tilting or rotation of the denture about the anchor points with jaw or biting motions will apply pressure or biting force to the underlying tissue and jawbone, causing discomfort and trauma to the underlying bone and tissue, and ultimately resulting in significant bone erosion. The rest surface or surfaces avoid or reduce this problem by accepting down or biting pressure from the denture. Since the rest surfaces are not positively anchored to the denture, they will not be pulled up or from side to side as a result of jaw motions, and will therefore be less likely to cause bone erosion or damage. The implant assembly is therefore intended to be used at appropriate locations in the jaw which would otherwise be subject to considerable down pressure and potential trauma from an implant such as a full or partial denture or cantilevered bridge. The rest factor surface will be shaped to ensure that it can accept down pressure from an overlying denture in various possible orientations, whatever the angle of the patient's jaw. The support surface prevents excessive force on the tissue, and thus protects the gum tissue from impacting forces which could cause soreness and trauma. Additionally, the rest or support surface prevents or reduces bone erosion by providing support to the distal end of the denture and resisting biting forces.

The implant assembly is designed for implantation at any position in the jaw where a rest factor or surface for a full or partial denture or bridge is needed. Normally, this will be in the posterior jaw, for example in between the first bicuspid and the second molar area, as illustrated in FIGS. **12** and **13**, but a rest surface may also be advantageous in other areas. The dimensions of the assembly **10** are selected according to the dimensions of the jaw in the area where the implant is to be used. A range of implant assemblies of different dimensions may be provided for fitting patients having different jaw dimensions. The implant member is designed to provide sufficient anchoring area with the jawbone when embedded in the jaw, while not extending too deeply into the jaw where it might otherwise interfere with the nerve. The implant member has a relatively large diameter, larger than typical straight cylindrical implants, but is shorter in length than such implants, preferably having an overall length in the range from 2 mm to 4.5 mm. In one specific example, several different size implants were provided with annular members of 4.25 mm, 5 mm, and 6 mm outer diameter, respectively. The rest factor may have a diameter of 4 mm. The extension or spigot **28** may also be provided in different sizes according to the position in the jaw where it is to be embedded. Central spigots of length between 1 mm and 3 mm may be provided. Also, the central spigot may be omitted in some cases where very little depth is available in the jawbone for embedding the implant. In this case, the rest factor **18** will also have no projection **40**. Rest factors having heads in a range of different sizes are also provided, for example, 3 mm, 4 mm and 5 mm. Generally, the overall implant assembly is very short, extending only from 2 to 4.5 mm into the jawbone, while the implant is shaped to have a relatively large bone to implant contact area, as best illustrated in FIG. **5**.

As can be seen in FIG. **5**, after osseointegration has taken place, there will be a relatively large area of bone to implant integration even though the penetration into the jaw bone is very short. The implant has first, circumferential surfaces **180, 182** which resist sideways movements of the dentures, while the second, lower surfaces **184, 185, 186** of the outer rim **30**, upper face, and boss **28** resist vertical movements. The two surfaces combine to provide maximum rest factor to bone contact with a relatively short distance of penetration into the jawbone. The grooves **29** in the outer surface will resist rotational movements of the implant. Thus, the implant surfaces resist lateral and vertical loosening movements, and the implant effectively becomes fully integrated with the bone.

This implant is sufficiently short to be safely inserted even where some bone erosion has already taken place, with the appropriate height implant member and rest factor being selected according to the bone depth and tissue height of the particular patient.

The method of inserting the implant **12** in the jaw will now be described with reference to FIGS. **6–11** of the drawings. This can easily be done by a dentist or dental surgeon. First, a bore shaped to correspond to the shape of member **12** must be cut out. This is done using a series of special cutting burrs. A first water cooled burr or cutter (not illustrated in the drawings) is used to drill a cylindrical guide hole or pilot dimple at the center of a selected site, for example under the second molar area or at the distal end of a cantilevered bridge. The width of the alveolar crest with equal distance on both sides of the pilot dimple is then measured. The largest diameter rest factor implant which will fit within the available width while allowing at least ½ mm of bone on each side of the implant is selected. An internally irrigated implant body drill **44** of diameter matching that of the selected rest factor implant is then selected. Burr **44**, illustrated in FIG. **6**, has a smaller diameter pilot drill **46** for cutting out a cylindrical bore **48** and a larger diameter portion **50** having an end cutter **52** for drilling out the larger diameter upper end **56** of the bore. The cylindrical portion **50** may be provided with suitable markings or a scale (not shown) so that the dentist can control the depth the drilled bore. However, in the preferred version, the height of portion **50** matches the height of implant member **12**. The length of the pilot drill **46** will correspond to the length of spigot **28** of the implant, so that spigot **28** will fit in bore portion **48**. The dentist determines the optimum angle and drills in to the bone to a point where the larger diameter portion **50** ends.

FIG. **7** illustrates the operation of a water cooled guided core drill or burr **58** having a central guide or pilot tip **59** for fitting in the previously drilled bore portion **48** to center the tool on the bore. The tool has a cylindrical central body portion **60** having a downwardly facing annular ring of cutting teeth **62** for drilling out an annular groove or channel **64** around the periphery of the flat or shoulder **66** separating counter bore **56** from the smaller diameter bore portion **48**. The length of the teeth controls the depth of groove **64**, and will be equivalent to the height of the downwardly depending rim **30** of the implant to be received in the bore. Once the lower face of body portion **60** hits the flat **66**, drilling is stopped.

All three cutting tools may be provided with a cage for collecting bone as it is drilled out of the bore. The collected bone may be used for filling any edges or spaces left after insertion of the implant.

After the bore for receiving the implant **12** has been prepared as described above, and debris has been cleaned out in the standard manner, for example by irrigating the site with sterile water or sterile saline, the implant **12** can be inserted. The healing screw **70** is initially secured to the implant.

Prior to insertion in the previously prepared bore, the internal faces of the implant will be coated with a suitable bonding agent, such as hydroxyl apatite. These faces may be roughened as illustrated in FIGS. **1** and **3** to increase the bonding area and strengthen the adhesion in the bore **14**. A suitable plastic insertion tool **67** (see FIG. **1**) having a handle and a gripping end for snap engagement over the head of the healing screw is then used to insert the implant and attached healing screw in the bore. The bore is drilled out to a depth such that the upper end of the implant **12** will be at the bone level when fully inserted, as indicated in FIG. **8**, or slightly below that level if desired. For convenience, the insertion tool is preferably a disposable, snap-off plastic member which is supplied in a sealed, sterile package together with the healing screw and implant, the three parts being supplied secured together in the package for easy handling. The insertion tool can be snapped off after the parts have been positioned in the bore.

The tissue or gum **21** is then secured over the implant and healing screw with conventional flap sutures **80**. Since the head portion of the healing screw projecting above the implant member is relatively short, little or no bulge will be apparent when the tissue is sewn up. The site is left to heal for several months to allow the implant to osseointegrate, or bond with the surrounding bone. At this time, a special locating tool **82**, best illustrated in FIGS. **4A**, **9** and **10**, is used to locate the implant.

The retrieval tool **82** comprises a central shaft **84** with a head or gripping handle **86** at one end. Handle **86** projects to one side of the shaft as indicated. A projecting probe **88** at the opposite end is designed for engagement in the bore **76** of healing screw. The probe has a sharp pointed end **91**. A cutter sleeve or tissue punch **92** is slidably mounted on shaft **84**. Cutter sleeve **92** has a projecting annular handle or gripping portion **94** and a lower cutting edge **96**.

The use of the retrieval tool **82** to locate the implant site will now be explained, with reference to FIGS. **1** and **9**. The approximate area of the implant is first located, utilizing radiographic charts and finger palpations. The pointed end **91** of the probe is then used to pierce the tissue **21** at the approximate site of the implant, and is then used as a probe to locate the upper face of the healing screw. Once the screw has been found, the concave recess (if provided) will act as a guide to direct the pointed end to the retrieval hole or bore **76** at the center of the healing screw, as illustrated in FIG. **9**, centering the tool on the implant site.

Once the probe has entered bore **76**, as illustrated in FIG. **9**, the handle **86** of the locating tool is held firmly in one hand to support the tool upright and the tissue punch is turned in a circular motion while pushing it down along the locating tool with a firm pressure. The tissue punch is designed to cut out a plug **97** of tissue directly over the implant. The punch will be stopped when it engages the outer diameter of the healing screw. The locating retrieval tool **82** is then removed together with the tissue punch, simultaneously pulling out the plug of tissue. If the tissue plug does not pull out, it may be removed with forceps.

A separate healing screw removal tool **110** is then used to remove the exposed healing screw. Tool **110** is illustrated in FIG. **4B** and **11**, and comprises a shaft portion **112** with a head or gripping portion **114** at one end and a threaded portion **116** at the opposite end for threaded engagement in the threaded, upper end portion **77** of bore **76** of the healing screw. The threaded end **116** is threaded counter-clockwise into the healing screw, tightening the tool inside the healing screw and at the same time unscrewing the healing screw from the implant as illustrated in FIG. **11**. The implant is thus exposed for secondary healing or restoration procedures.

This technique for exposing or recovery of an embedded implant after healing and osseointegration has taken place removes only a small plug of tissue from immediately above the implant site, avoiding the need to cut out an enlarged flap of the tissue both to locate the implant and to expose the healing screw for removal. Little or no suturing will be required. Thus, considerably less trauma to the tissue is involved, reducing the healing time and the risk of infection. Also, the healing screw is located and the tissue plug may be removed simultaneously with one tool, simplifying the procedure and reducing the time involved. The method involves the use of a specialized healing screw with a bore in its upper surface, together with a special locating and retrieval tool. It may be used not only for location of the implant **12** as described above, but also for locating any conventional cylindrical implants in implant dentistry, replacing the conventional healing screws of such implants with a healing screw as illustrated in FIG. **1** but having a stem or shaft designed for fitting into the implant bore. Although in the preferred embodiment described above, the upper end of the retrieval bore **76** in the upper face of the healing screw is screw threaded, it may alternatively be hexagonal with the retrieval tool having a corresponding hexagonal portion for mating engagement in the bore.

As an additional aid in locating the embedded implant, a thread or wire may be left projecting from the heading screw through the suture area, so that the location may be found easily after healing. Alternatively, the tissue overlying the implant may be marked with a suitable dye. However, it is expected that such markers will not normally be required, the dentist locating the general implant site by feel before piercing the tissue with the probe.

The same implant recovery tools may be used for any selected implant size, since the dimensions of bore **76** in the healing screw will be identical.

Once the healing screw has been removed and the exposed surface of the implant suitably cleaned and prepared, the appropriate rest factor **18** is inserted into the implant. The rest factor **18**, in addition to providing a rest surface, also acts as a secondary tissue healing insert. The rest factor is selected with a head height so that it will project just above the patient's tissue level when installed. The shaft **38** of rest factor **18** is screwed into bore **32** of implant **12**, as indicated in FIG. **5**, with the mating surfaces first being coated with a suitable bonding agent.

Although the rest factor in the preferred embodiment has a head portion preformed in a range of heights, it may alternatively be provided with a longer extension piece which projects above the tissue level **20** when the member **18** is fully inserted. In this case, the dentist marks around the periphery of the selected member **18** at the tissue height, and removes the member from the implant. A suitable temporary cover or crown of a standard nature may be fitted into implant **12** at this point.

The dentist then mounts the member **18** in a previously prepared cast of the patient's jaw, and machines or cuts away the upper face of member **18** to provide the desired rest surface **22** at the tissue level **20**, as determined by the markings made while the member was mounted in the patient's jaw. The cut away surface may be slanted or inclined according to the angle of the patient's tissue or gum. This allows the height to be customized for minimal side torque. The shape of the rest surface **22** may be of the dentists choice. For example, it may be concave, while the denture or prosthesis with which it is to cooperate has a corresponding convex area or bump **95** for fitting into the concave depression on the rest surface, so that the rest factor or member **18** accepts down pressure from the denture without any retention. However, in the preferred embodiment, members **18** with ready-made ball-shaped or other shape heads of various sizes in a range of tissue heights are provided to avoid the need for machining on site by the dentist.

This procedure may be utilized to implant one or more rest factors at any suitable location in the jaw, depending on the denture pressure points, for example as illustrated in FIGS. **12** and **13**.

FIG. **14** of the drawings illustrates an alternative embodiment of the implant assembly which is much thinner than that of FIGS. **1–3** and **5** and which will therefore project only a minimal distance into the jawbone, further reducing the risk of interference with the nerve. This implant assembly is useful for providing a rest surface at a desired location in any patient's jaw, whether or not previous bone erosion is a factor, but is particularly useful in patients having significant bone erosion where very little depth is available for implants.

FIG. **14** illustrates an implant member **180** and healing screw **182** of an implant assembly according to a second, modified embodiment of the invention. FIG. **18** illustrates the implant member **180** and healing screw **182** of FIG. **14** implanted in the jawbone during the osseointegration process, while FIGS. **15–17** illustrate a modified method of forming a bore in the jawbone for receiving the implant.

As illustrated in FIGS. **14** and **18**, implant member **180** is a flat disc-like member having an undersurface of similar shape to the undersurface of member **12** in the first embodiment. However, the peripheral rim **184** and central spigot **186** are approximately the same length in this embodiment, so that the spigot **186** does not project downwardly below the lower end of rim **184**. Preferably, member **180** has a total height of around 2 mm while its peripheral rim **184** projects around 1 mm below the undersurface of disc part **188**. The member **180** is provided in a range of diameters, preferably 4.25 mm, 5 mm and 6 mm, for patients having varying alveolar ridge widths. As in the first embodiment, the maximum diameter possible implant member is selected for the patient dependent on the available space, i.e., the alveolar ridge width. The rim **184** is relatively thin, and in one particular example had a thickness of the order of 0.4 mm.

The member **180** has a recess **190** in its upper surface with a taper **191** extending around the outer periphery of the recess. A central, straight cylindrical bore **192** extends from the center of recessed area **190** into the spigot **186**, and bore **192** has screw threads **193** extending along its length. Member **180** is made of the same material as the implant **12** of the first embodiment. As in the first embodiment, circular or rounded indents **194** are provided on the outer surface of member **180** to resist rotational movement after implantation. Between six and eight equally spaced indents may be provided, for example.

Healing screw **182** has a relatively short head portion **195** and a downwardly depending, screw threaded shaft portion **196** for mating engagement in the bore **192** of implant member **180**, as illustrated in FIG. **18**. The undersurface of head portion **195** seats in recessed area **190** and has a tapered annular surface portion **197** for seating on taper **191** around the recessed area **190**, for accurate seating of the screw in bore **192**. The upper surface of head **195** has a central, tool receiving bore **198** for receiving the end of a suitable tool for inserting the arrangement in a previously prepared bore in the jawbone, and also for receiving the end of locating tool **82** as described above in connection with the first embodiment of the invention. Bore **198** is of hexagonal cross-section, and is designed to be removed by a suitable removal tool having a hexagonal end after location by tool **82**.

The rest factor or member of the second embodiment is not illustrated in the drawings but will be similar or equivalent to rest factor **36** as illustrated in FIGS. **2** and **5** of the drawings apart from its lower surface and downwardly depending shaft portion, which will be identical to lower surface and shaft portion of the healing screw **182** for mating engagement in the bore **192** in implant member **180** after osseointegration is complete.

The modified method of inserting insert member **180** in the jaw will now be described with reference to FIGS. **15–17** of the drawings. This procedure can easily be carried out by a dentist, although a dental surgeon may also perform the procedure if desired. After the tissue overlying the implant site has been cut, a pilot dimple is formed at the center of the selected site. The width of the alveolar crest or ridge at the implant site is measured, and the largest possible diameter implant which will fit within the available width while leaving at least ½ mm of bone on each side is selected.

A bore matching the selected implant dimensions is then accurately drilled out using a series of three internally irrigated drilling burrs. The first burr **210** has a straight pilot drill **212** for drilling out a cylindrical bore **214** to a desired depth at the implant site, as determined by stop **216**, as illustrated in FIG. **15**. Preferably, bore **214** will be slightly longer than the implant member, for example 3 mm. A second burr **218** is designed to cut out the desired bore shape to match the shape of the undersurface of implant member **180**, as illustrated in FIG. **16**. Burr **218** has a central, non-cutting guide or spigot **220** for fitting into previously drilled bore **214** for centering purposes, a first cutting surface **222** for cutting down to the level of flat **224**, and an annular, downwardly projecting rim of cutting teeth **226** for cutting out part of annular recess **228** for receiving the annular rim **184** of the implant member. Preferably, teeth **226** are designed to cut recess **228** to a depth of ½ mm. The final burr **230** is illustrated in FIG. **17** and is designed to finish and smooth the surfaces of recess **228**. Burr **230** also has a central guide **231** and an annular rim of finer cutting teeth **232** which cut the final ½ mm of the recess to a total depth of around 1 mm, and which smooth and finish the cut surfaces.

The finished bore of FIG. **17** is cut to very precise dimensions by the series of cutting drills so that the implant member can be accurately seated in the bore as illustrated in FIG. **18** after suitable treatment of the surfaces and application of bonding agents. The gap below spigot **186** does not affect the integration process and will soon fill in with bone. The accurate, close fitting of peripheral rim **184** into recess **228** provides great stability and resistance against any sideways movement during the three-month or more osseointegration period, so that a good bone-to-implant bond can be produced in spite of the minimal length of the implant.

After osseointegration is complete, the site is located and the healing screw **182** exposed and removed as described above in connection with the first embodiment of the invention. The rest factor (not illustrated) is inserted into the implant member as described in connection with the previous embodiment.

In both of the embodiments described above, the shape of the undersurface of the implant ensures that there will be little or no side sway either during or after the osseointegration period. This results from the downwardly projecting peripheral rim, having inner and outer circumferential surfaces which combine to resist any sideways forces. This resistance to side-sway is enhanced by the spigot **186** which also acts to resist sideways movement. The relatively large diameter of the implant provides a large area of downwardly facing surfaces which together resist downward forces on the implant assembly, further increasing the stability of the implant and acting to absorb biting pressures. The implant is selected to be of the maximum possible diameter according to the bone width available for implantation in a particular patient. The indents **29**, **194** will act to resist rotational movements during and after osseointegration. The combined effect of the shape of the undersurface of the implant and its relatively large surface area is to produce a very stable implant with minimal penetration into the bone.

Although the implant member is illustrated as implanted so that its upper surface is at the bone level, it may be implanted to a lesser depth if the patient has a large amount of bone erosion or resorption. For example, if there is only 1 mm bone depth available for implantation without fear of interference with the nerve, the implant is simply installed to 1 mm in depth so that approximately 1 mm projects above the bone level. However, it will still have sufficient holding power to remain in position since the undersurface, and particularly the peripheral rim, will position the implant during osseointegration and bond to the surrounding bone to resist sideways and downwards forces. Since it is not anchored to any overlying body, upwards forces do not have to be resisted. Thus, sufficient bonding area is provided to resist any loosening during normal wear.

This implant system and method may be used in any implant procedure where a denture or prosthesis of more than one tooth is involved, and is particularly useful in posterior areas of the jaw where the implant depth is limited, for example the second molar area, and in conjunction with anterior implants or cantilevered bridges. The implant has a relatively short penetration into the bone, so that it can be installed in regions to the rear of the first bicuspid without fear of interference with the nerve, yet has sufficient anchoring surface area to integrate with the bone and accept down pressure of two to three hundred pounds from an overlying denture or prosthesis. Since the implant is not positively anchored to the prosthesis, it does not have to resist large upward or sideways forces, reducing the risk of bone erosion. At the same time, the rest factor will reduce the trauma to underlying tissue and reduce or eliminate bone erosion from the overlying denture by accepting the downward pressure from the denture.

The implant recovery method and tool described above will eliminate the need to locate and expose osseointegrated implants by a surgical flap technique. The locating tool and guided tissue punch accurately locate the implant with minimal trauma, and remove only a plug of tissue directly above the implant sufficient to expose the healing screw for removal. The amount of trauma and bleeding is reduced and the tissue around the implant site remains virtually intact.

FIG. **19** illustrates a rest factor **250** according to another embodiment of the invention. The rest factor **250** is generally cylindrical and has an upper, dome-shaped portion **252** and a downwardly depending, threaded stem portion **254**. The dome portion **252** has hex bore **256** formed in its upper end for gripping by a hex tool on installing or removing the rest factor **250**, as will be explained in more detail below. The hex bore will be relatively small, preferably of the order of 0.050", and may be filled with a temporary sealant after installation.

The rest factor **250** is made from a suitable metal such as titanium alloy. The dome portion has a wear resistant titanium nitride coating applied. Rest factors are provided in a range of different dimensions. The dome portion is preferably provided in a range of different heights, and in a preferred embodiment rest factors were provided with dome portions of height 1.5 mm, 2.5 mm and 3.5 mm for fitting patients with different gum thicknesses. The total height of the rest factor is preferably in the range 2 mm to 4.5 mm.

FIGS. **20**, **21** and **22** illustrate three alternative types of implant for implanting in the jaw bone at a selected site to receive rest factor **250** or other denture fitting devices Such as denture anchors or magnetic abutments of a conventional type. The implant **260** of FIG. **20** is relatively short and has a body of generally cylindrical shape having an upwardly tapering upper end portion **262** and a downwardly depending stem portion **264**. A threaded bore **266** extends downwardly from the upper end of the implant for receiving the threaded stem portion of the rest factor **250**. An eight-sided cut **268** extends through the threads, as illustrated in FIGS. **20** and **23**. The outer diameter of the implant at its upper end **270** is dimensioned to match the outer diameter of the dome portion of the implant at its lower end **272**.

The stem portion **264** of the implant **260** has an annular recess **274** extending upwardly from its lower end to a position close to but offset downwardly from the lower end of the recess **268**. Recess **274** forms an outer annular rim **276** and a central boss **278** at the lower end of the implant, and provides an area for bone growth and osseointegration upwardly into the implant. Thus, the implant is generally cup-shaped at its lower end, with a central protrusion in the cupped area. A triple lead screw having a first lead or thread **279**, a second thread **280**, and a third lead or thread **282** is formed around the outside of the stem portion **264**. The threads **279**, **280**, **282** are preferably of square cross-section and project out a predetermined distance from the surface of the stem portion **264**. The threads may each extend around approximately 180° and preferably do not overlap, although they may overlap in alternative embodiments.

FIG. **21** illustrates another implant **284** which is longer than that of FIG. **20**. Again, the implant is generally cylindrical and has a relatively thin upper annular portion **286** with a short, upwardly projecting and tapered rim **288** and a downwardly depending stem portion **290** of reduced diameter. A bore **292** projects downwardly from the upper end of the implant **284** and has a threaded portion **294** for receiving the threaded stem of a rest factor member. A ten-sided or decagon cut **296** is formed through the threads, and preferably extends about halfway down the bore **292**. In this version, the bore **292** projects downwardly into the stem portion of the implant, since the upper portion **286** and rim **288** are shorter than those of implant **260**.

A triple lead thread having first, second and third threads **297**, **298** and **299** is formed around the outer surface of stem portion **290**. Preferably, the threads **297**, **298** and **299** start at equally spaced intervals around the periphery of the stem portion adjacent its upper end but spaced downwardly a distance below the annular ring portion **286**. The threads

extend around the stem portion towards its lower end and terminate at a location spaced above the lower end of the stem portion. As in the version of FIG. **20**, the stem portion **290** has an annular recess **300** at its lower end forming an annular rim **302** and central boss **304**. As in the previous embodiment, the upper end **306** of the implant is of diameter matching that of the lower end of the rest factor.

FIG. **22** illustrates another, longer implant **310** which is similar to that of FIG. **21**, apart from the fact that the stem portion **312** is longer and a quadruple lead screw is provided on the stem portion. The implant of FIG. **22** is otherwise identical to that of FIG. **21** and like reference numerals have been used for like parts. The implant has a bore identical to that of implant **284** extending downwardly from its upper end, and an annular recess at its lower end which is identical to the recess of implant **284**. As in the previous two embodiments, the upper end **304** of the implant has a diameter matching that of the lower end of the dome portion of the rest factor.

A series of four separate threads **314**, **316**, **318** and **320** is provided around the periphery of the stem portion **312**. The threads start at equally spaced intervals around the periphery of the stem at a location close to but spaced slightly below the upper end of the stem portion, to leave a gap between the annular ring **286** and the threads. The gap is in the range from 1 mm to 2 mm.

Although in the illustrated embodiment the implants **260** and **284** each have three threads, and the longest implant has four external threads, any one of these implants may have two, three or four threads. The double, triple or quadruple lead thread allows for quick and solid engagement into a tapped bone site. The projecting screw threads form an undercut region and bone growth and attachment in this area increases the strength of the attachment and resistance to loosening forces. The unique cup shaped recess design at the lower end of the implant is also designed to increase bone to implant surface contact and attachment area.

The pitch or angle of the thread is preferably relatively steep and is preferably in the range from around 9° to 17°. The spacing between adjacent threads is preferably at least 1 mm. It has been found that this is the minimum spacing required to ensure significant bone growth and osseointegration in the gaps between threads. The threads preferably project out around ½ mm from the surface of the stem portion of the implant, and they are about ½ mm in height. Thus, the gaps between the threads are twice as wide as the threads themselves. This provides good blood supply to the bone between the threads, and provides a greater bone thickness and stronger shelf of bone between the threads.

Both the implants and the rest factor are all made in a range of lengths and diameters to fit the size of different patient's jaws. Implants will be provided in a range of lengths. Preferably, the lengths are of the order of 2 mm, 4.5 mm, 7 mm, 10 mm and 13 mm. The 2 mm length implant will be of the type illustrated in FIG. **20**, while the 4.5 mm implant will be of the type illustrated in FIG. **21** and the 7 mm, 10 mm and 13 mm implants will be as illustrated in FIG. **22**. Each of the different implants will be provided in a range of different outer diameters, preferably 4 mm, 5 mm and 6 mm. Preferably, the height of the tapered rim of the implant **260** or **310** is as short as possible, for example around 0.5 mm.

The implants are made of a suitable material such as titanium and may be coated with a coating of a material for improving bone adhesion.

The method of installing implants **260**, **284** and **286** will be similar with appropriate changes in the dimensions of the drilled bore to accommodate the different length stem portions and numbers of threads. The method will therefore be described for the implant **260** only, by way of example. The implantation method is similar to that illustrated in FIGS. **6–11** and described above.

The first step in the implant procedure is to select the site in the jaw at which the implant is to be installed. The appropriate height and diameter implant member is selected dependent on the bone depth, tissue height, and jaw thickness at the selected site. The minimum bone depth required is 1 mm between the bottom end of the installed implant and the mandibular nerve canal or maxillary sinus space. Thus, the total bone depth required for installing the 2.5 mm implant is only 3.5 mm, while the longer implants can be installed where a greater bone depth is available. The minimum bone width required to place a rest factor implant is ½ mm each on the lingual and facial sides of the implant, requiring a 5.0 mm total ridge width for the 4.0 diameter implant, 6.0 mm ridge width for the 5.0 mm diameter implant, and 7.0 mm ridge width for the 6.0 mm implant. Based on these dimensions, the appropriate implant can be selected.

The very short, 2.5 mm implant can be installed safely even where some bone erosion has already taken place and even in the distal jaw regions without risking interference with the mandibular nerve. The design is such that the implant has a relatively large surface area for bone to implant osseointegration, and undercut areas for improved retention and resistance to movement in any direction.

Once the appropriate implant has been selected, a bore shaped and dimensioned to correspond to the shape and dimensions of the implant is cut out. This is done in a series of steps. First, a mesio-distal incision is made through the tissue or gum **321** along the alveolar mid-crest at the selected site, typically the area of the second molar. A bone plateau is created which is made as flat as possible by removing ridges or other bone irregularities. At this point, the width of the alveolar crest can be measured to determine the largest diameter rest factor implant which can be fitted within the available width and still allow at least ½ mm of bone on each side. The implant is placed as close as possible to the lingual side while still allowing the ½ mm of bone on the lingual side.

At this point, a pilot burr is used to drill out a pilot hole of appropriate depth at the center of the insertion site, as illustrated in FIG. **15** above. The pilot hole diameter will be substantially identical to the diameter of the implant central boss **278**. An appropriate depth limiting sleeve is used with the pilot burr in order to limit the depth of the pilot hole to match the implant height. Thus, depth limiting sleeves will be provided for each of the four different implant heights, and the appropriate sleeve will be selected on installation. The lower end of a previously drilled pilot hole **322** in jawbone **323** can be seen in FIG. **24**, which illustrates a subsequent step in the procedure.

An alignment pin may be placed in the pilot hole to check for proper alignment to the path of a prosthetic insertion and between multiple implants.

After alignment, a spot-face drill (not illustrated) is used to make a shallow, 360° shoulder or seat **324** into the crest of the bone. This seat is used to assist in engaging of a bone tap in a later stage of the procedure. The drill is withdrawn several times during site preparation to remove bone buildup between the flutes of the drill. An implant body drill is used to drill out the main recess **328** for receiving the implant. This drill will be similar to drill **44** illustrated in FIG. **6**,

above, and will have a diameter corresponding to that of the stem portion of the selected implant. Thus, the drill will have a diameter equal to the implant diameter less the thickness of the threads, or 4.0 mm in the case of a 5.0 mm implant, for example.

In the next step of the procedure, a core drill **326** is used to cut an annular ring or recess **330** at the bottom of recess **328** for receiving the underside rim **272** of the implant. Drill **326** has a central guide **332** for centering in the previously drilled pilot hole **322**, a cylindrical central body portion, and a downwardly facing annular ring of cutting teeth **334** for drilling out an annular groove or recess **330** for receiving the rim **272** (or **302** in the case of the implant **284** or **310**) of the implant.

A series of three guided hand taps (starting tap, intermediate tap and finish tap) are used to make a multiple lead tapped preparation into the drilled hole **328**. It will be understood that the triple and quadruple leads will be made in a similar manner. One of the thread taps **336** is illustrated in FIG. **25**. Each tap has a tap guide pin **338** which engages the pilot bore to keep the tap centered on the recess. Optionally, a tap guide template (not illustrated) may be secured across the recess via pins secured on opposite sides of the implant site. This can be used to provide better support for the bone tap if the patient has spongy, cancellous bone. The tap **336** has triple lead cutting flutes **340** for forming a thread matching that on the insert. The starting tap has a machined line indicating the start of the double cutting edge of the bone tap. The starting tap is positioned into the drilled recess and the cutting flutes are engaged into the cortical bone, with the machined line on the tap positioned perpendicular to the longitudinal axis of the ridge. The implant site is then hand tapped and threads **342**, **343** and **345** are tapped into the recess. The tap is backed off a quarter of a turn several times during the process to clear bone chips. In this way, the tap is worked down to the bottom of the drilled recess **328**.

The procedure is then repeated using an intermediate tap, which will be marked with two lines to distinguish from the other two thread cutting taps. The lines are positioned in the same starting position as the line on the starting tap. Finally, the procedure is repeated with the finish tap, which will be marked with three lines, to create a final cut of the bone thread to accept the implant.

An octagonal wrench **344** is used to place the implant into the prepared implant recess, as illustrated in FIG. **26**. The octagonal end of wrench **344** will engage in the octagon **268** cut through the threads **266** and will not damage the threads in bore **266**. The implant is completely seated with the implant threads completely engaged in the bone threads and the tapered upper portion of the implant projecting above the level of the bone, as illustrated in FIG. **26**. If the implant is set in correctly, the stem portion **264** will have its upper end located ½ to 1 mm below the top of the bone, as illustrated in FIG. **26**.

A healing screw is then threaded into the implant to protect the internal threads of the implant during the osseointegration period. The healing screw is similar to the healing screw **70** of the first embodiment but with a threaded stem matching bore **266** and a hex hole in place of threaded hole **76** at the upper end of the screw. The flap of gum **321** is sewn down over the implant site, in a similar manner to that illustrated in FIG. **8** above, after installation of the healing screw.

The implant is then left for a healing period to allow the bone to osseointegrate with the surface of the implant. A healing period of not less than 4½ months should be used. The bone will grow over and osseointegrate into the gaps between the threads, providing a greater osseointegration surface area and better retention of the implant. The cup-shaped design of the lower end of the implant, along with the multiple lead threads, increases bone to surface contact and helps to withstand posterior occlusal load.

Where a triple or quadruple lead thread is used, resistance to rocking or movement of the implant is provided. With two opposing threads, there may be some tendency for the implant to rock from side to side. Thus, implants with three or four threads are used for even greater resistance to rocking as a result of loads.

After the minimum period required for osseointegration, an incision is made over the implant for access to the healing screw. Radiographic charts and finger palpation may be used to locate the general area of the implant. The incision may be made in a conventional manner, but preferably a guided tissue punch **82** is used as in the previous embodiments. The tissue is pierced with the sharp point or probe **91** of the tissue punch, and the implant site is probed until the point **91** locates a hex hole provided on the top of the healing screw. The guided tissue punch **92** is then turned down on the guide with firm pressure until it punches an opening through the tissue or gum. The tissue punch will engage the outside diameter of the healing screw, and will cut out a plug of tissue directly over the center of the implant, as illustrated in FIG. **10** above.

The locating tool/tissue punch assembly is then removed, simultaneously pulling out the cut plug of tissue. If the tissue does not pull out with the tissue punch, forceps may be used to remove it and expose the healing screw. A cover screw hex tool (not illustrated) is used to engage the hex hole at the top of the cover screw and remove the cover screw from the implant.

The implant is now exposed for attachment of the dome-shaped rest factor **250** as illustrated in FIG. **27**. The implant may alternatively be attached to other dental devices, such as implant anchors or magnetic abutments for dentures. The dimensions of the selected rest factor will depend on the implant dimensions and also the tissue height of the patient. The height of the implant should be such that the top of the dome is at the tissue level or only slightly above it. The dome portion of the rest factor selected should therefore have a height substantially equal to the tissue or gum thickness. If the gingival layer has a height substantially greater than the largest dome portion, tissue reduction must be used to reduce the gingiva thickness to a maximum of 3 mm at the implant site.

Once the correct size rest factor has been selected, a hex wrench **346** having a hexagonal shaft **348** is used to engage the hex bore **256** at the upper end of the dome-shaped upper end portion **252** of the rest factor. The rest factor is then threaded into the bore of the implant, as illustrated in FIG. **27**. The tissue is then sewn back around the implant dome, as indicated in dotted lines in FIG. **27**, and the dome is left in place for around 4–6 weeks to allow for a period of reduced implant loading during gingival healing. The patient's denture should be fitted to the dome top with a soft reline material to maintain proper occlusion during the gingival healing period. This is done by taking a full arch reline impression including the exposed metal tip of the rest followed to prepare a master cast of the jaw including the exposed tip of the dome. The denture base is relined using this cast in the normal manner.

If a change in tissue height has occurred during the tissue healing period, the rest factor may be unthreaded and replaced with another rest factor of the correct dimensions.

Once the healing period is complete, the top of the dome is exposed for a prosthesis to rest on with lateral freedom of movement. The preferred arrangement is to use the dome as a permanent, non-retentive rest when the patient has existing anterior retention for a prosthesis. However, the rest factor may be used as an attachment if required, for example if there is no existing retentive means for the prosthesis, or lateral stability is needed due to severely reduced ridge height. A hole is drilled into the center of the dome to an appropriate depth, and resin is injected into the counter-bore. When the resin starts to become firm, a post forming part of a standard rest plate of a denture is inserted into the bore until the bottom of the plate comes into contact with the resin.

FIGS. **28** and **29** illustrate a modified insert **350** for use with a rest factor **250** in an equivalent manner to that described above. However, rather than having a multi-faceted cut for receiving a wrench in the threaded bore **352** of insert **350**, an external, twelve-sided wrench element **354** is secured to the upper end of insert **350**. Element **354** has an outer twelve-sided surface **356** for engaging a wrench with a corresponding internal bore, and a through bore **358** coaxial with threaded bore **352** but of larger diameter. Element **354** is preferably formed separately from insert **350** and then pressure bonded or welded to it. A conventional hex wrench may also be used to engage the element **354**.

Apart from threaded bore **352** and wrench element **354**, insert **350** is otherwise identical to that of FIG. **21** and like reference numerals have been used as appropriate. It will be understood that a wrench element **354** may also be provided on the insert of FIG. **20** or FIG. **22** in place of the multi-sided internal cut. This avoids the need for a precision machined cut extending through the threads, where the cut must be of precise dimensions between those of the inner and outer diameter of the threads to avoid damaging the threads.

The use of an implant having two or more stabilizing threads on the outer surface of the stem embedded in the jawbone, combined with the inverted cup shape of the lower end of the implant, provides a stable implant which resists movement even in the case of the very short version. Bone growth into the inverted cup and between the threads provides a large area of bone to implant contact and osseointegration, providing significant resistance to both lateral and downward forces both during and after the osseointegration period.

The non-retentive rest factor can be used to support dentures non-retentively in the posterior area of the jaw. As a result, the pressure applied to the lower jaw by the denture during mastication is dramatically reduced, reducing the discomfort and bone erosion normally resulting from denture wear. Although the implant can be installed anywhere in the jaw for retentive or non-retentive engagement with a denture or prosthesis, it is particularly useful for providing support in posterior regions of the jaw where the jawbone has become eroded. The accepted formula for cantilevered dentition attached to anterior implants limits the extension of the cantilever over the posterior ridge to no further than the distance between the plane of the most anterior implant and the furthest posterior implant. This results in a lack of support under the molar dentition and an extraction effect on the anterior implants during masticatory function. With the additional support provided by one or more rest factors and implants in posterior regions of the jaw, the extraction effect is significantly reduced or eliminated. In addition, trauma to the ridge under occlusal load, and the resulting bone loss, may be reduced.

Although some preferred embodiments of the present invention have been described above by way of example only, it will be understood by those skilled in the field that modifications may be made to the disclosed embodiments without departing from the scope of the invention, which is defined by the appended claims.

I claim:

1. A dental implant assembly for supporting as a rest factor the distal end of a denture anchored elsewhere in the jaw, comprising:

implant means for embedding in the distal region of the jawbone including a first part for projecting into and osseointegrating with the jawbone and a second part for projecting up to just above the tissue level;

the first part being relatively thin and having a predetermined height less than the distance between the top of a patient's jawbone at the implant site and the underlying region of the mandibular nerve;

the second part having an upper rest surface for supporting but not being connected to overlying portions of a denture anchored elsewhere in the jaw to resist biting pressure on the tissue and bone; and

the first part comprising a thin disc-shaped member having a downwardly projecting annular rim and a central spigot projecting downwardly from the disc-shaped member.

2. The assembly as claimed in claim **1**, wherein said first part comprises an implant member and the second part comprises a rest factor releasably securable to the implant member.

3. The assembly as claimed in claim **2**, including a plurality of implant members in a range of different sizes, the members having outer diameters in the range from about 4.25 to 6 mm.

4. The assembly as claimed in claim **2**, including a plurality of implant members in a range of different heights from 2 to 4.5 mm.

5. The assembly as claimed in claim **1** wherein the first part has a height no greater than its diameter.

6. The assembly as claimed in claim **1**, wherein the first part has a selected diameter slightly less than the width of the alveolar crest at the implant site.

7. The assembly as claimed in claim **6**, wherein the selected diameter is 1 mm less than the width of the alveolar crest.

8. The assembly as claimed in claim **1**, wherein the first part has a height no greater than 4.5 mm.

9. The assembly as claimed in claim **8**, wherein the first part has a height of between 2 to 4.5 mm.

10. The assembly as claimed in claim **1**, wherein the rest surface has a shaped, cooperating area for non-retentive seating engagement with a correspondingly shaped mating surface on an overlying denture.

11. The assembly as claimed in claim **1**, wherein the first part has a central bore in an upper face of the disc-shaped member.

12. The assembly as claimed in claim **11**, wherein the second part comprises a shaft portion for engagement in the central bore of the implant member and a solid head portion projecting upwardly from the shaft portion.

13. The assembly as claimed in claim **12**, wherein the extension portion is generally cylindrical with an upper, convex rest surface.

14. The assembly as claimed in claim **11**, wherein the bore has an upper threaded portion and a non-threaded, lower extension portion, the second part having a shaft portion with a corresponding threaded upper portion and non-threaded lower portion for mating engagement in said implant member bore.

15. The assembly as claimed in claim 14, wherein said implant member bore and rest factor shaft portion have upper ends having matching tapers.

16. A dental implant assembly for supporting as a rest factor the distal end of a denture anchored elsewhere in the jaw, comprising:

implant means for embedding in the distal region of the jawbone including a first part for projecting into and osseointegrating with the jawbone and a second part for projecting up to just above the tissue level;

the first part being relatively thin and having a predetermined height less than the distance between the top of a patient's jawbone at the implant site and the underlying region of the mandibular nerve;

the second part having an upper rest surface for supporting but not being connected to overlying portions of a denture anchored elsewhere in the jaw to resist biting pressure on the tissue and bone;

the first part comprising a thin disc-shaped member having a downwardly projecting annular rim; and

axially extending spaced grooves in the outer surface of the annular rim for restricting rotation of the embedded implant.

17. A dental implant assembly for supporting as a rest factor the distal end of a denture anchored elsewhere in the jaw, comprising;

implant means for embedding in the distal region of the jawbone including a first part for projecting into and osseointegrating with the jawbone and a second part for projecting up to just above the tissue level;

the first part being relatively thin and having a predetermined height less than the distance between the top of a patient's jawbone at the implant site and the underlying region of the mandibular nerve;

the second part having an upper rest surface for supporting but not being connected to overlying portions of a denture anchored elsewhere in the jaw to resist biting pressure on the tissue and bone;

the first part comprising a generally cylindrical member having a downwardly depending annular rim, and a central spigot projecting downwardly from the cylindrical member, the central spigot having a length in the range from 1 to 2 mm.

18. A combined denture and support assembly, comprising:

a denture of more than one tooth;

an anchor securing one end of the denture to the jawbone;

support means for freely supporting a distal region of the denture at a selected location to the rear of the first bicuspid, the support means comprising a first part for embedding in the jawbone at the selected location and a second part for projecting up to at least the tissue level, the second part having an upper rest surface for supporting but not being connected to the denture and for accepting biting pressure from the denture; and

the first part comprising a thin disc-shaped member having a downwardly projecting annular rim and a central spigot depending downwardly from the disc-shaped member to define an annular cavity between the spigot and rim.

19. The assembly as claimed in claim 18, wherein said first part extends no more than about 4 mm into the jawbone.

20. The assembly as claimed in claim 19, wherein said first part has a diameter in the range from 4 mm to 6 mm.

21. The assembly as claimed in claim 18, wherein said second part extends up to between ½ to 1 mm above the tissue level.

22. The assembly as claimed in claim 18, wherein the first part comprises a flat, disc-shaped member having a downwardly projecting peripheral rim.

23. The assembly as claimed in claim 22, wherein the first part has a height of 2 mm and the rim projects 1 mm below the undersurface of the disc-shaped member.

24. A dental implant assembly for embedding in the jawbone of patient, comprising:

an implant member for embedding in and osseointegrating with the jawbone of a patient at a selected site;

an attachment member for securing to the implant member after osseointegration;

the implant member having an upper end portion with a central bore, the attachment member and central bore of the implant member having interengageable securing means for releasably securing the attachment member to the implant member, and a stem portion depending downwardly from the upper end portion for engagement with a recess in the jawbone of shape and dimensions matching those of the stem portion;

the stem portion having an annular indent at its lower end;

the stem portion having outwardly projecting screw threads; and

the threads comprising multiple lead threads.

25. The assembly as claimed in claim 24, wherein the threads comprise triple lead threads.

26. The assembly as claimed in claim 24, wherein the threads comprise quadruple lead threads.

27. The assembly as claimed in claim 25, wherein the threads are of square cross-section.

28. The assembly as claimed in claim 24, wherein the spacing between adjacent threads is at least 1 mm and the threads run parallel to one another.

29. The assembly as claimed in claim 28, wherein the gap between adjacent threads is larger than the width of each individual thread.

30. The assembly as claimed in claim 24, wherein the threads project out to a distance of ½ mm from the surface of the stem portion.

31. The assembly as claimed in claim 24, wherein the stem portion has an upper end and a lower end and the threads start at a position spaced below the upper end of the stem portion.

32. The assembly as claimed in claim 31, wherein the threads terminate at a position spaced above the lower end of the stem portion.

33. The assembly as claimed in claim 24, wherein the central bore projects downwardly into the stem portion of the implant member.

34. The assembly as claimed in claim 24, wherein the upper end portion of the implant member comprises an annular ring and an inwardly tapering rim projecting upwardly from the annular ring.

35. The assembly as claimed in claim 24, including a wrench element projecting from the upper end portion of said insert member for engagement with a tool for inserting the implant member, the wrench element having a bore aligned with the central bore of said insert member.

36. The assembly as claimed in claim 35, wherein the wrench element has a twelve-sided outer wrench engaging surface.

37. The assembly as claimed in claim 24, including a plurality of implant members in a range of different heights from 2 to 13 mm.

38. A dental implant assembly for embedding in the jawbone of patient, comprising:

an implant member for embedding in and osseointegrating with the jawbone of a patient at a selected site;

an attachment member for securing to the implant member after osseointegration;

the implant member having an upper end portion with a central bore, the attachment member and central bore of the implant member having interengageable securing means for releasably securing the attachment member to the implant member, and a stem portion depending downwardly from the upper end portion for engagement with a recess in the jawbone of shape and dimensions matching those of the stem portion;

the stem portion having an annular indent at its lower end; and

the attachment member comprising a rest factor member having an upper rest surface for supporting, but not being connected to, overlying portions of a denture anchored elsewhere in the jaw, the rest factor member having an upper, dome-shaped portion and a downwardly depending stem portion for engagement in said implant member bore, the rest surface comprising the upper end of said dome-shaped portion.

39. The assembly as claimed in claim **38**, including a plurality of rest factor members having dome-shaped portions of different heights in the range from 1.5 mm. to 3.5 mm.

40. The assembly as claimed in claim **39**, in which said rest factor members have total heights in the range from 2 mm. to 4.5 mm.

41. The assembly as claimed in claim **38**, wherein said dome-shaped portion has a hex indent at its upper end for engagement with a hex tool for insertion of the rest factor member into an implant member bore.

42. An implant member for embedding in a patient's jawbone for attachment to other dental devices, the member comprising:

a generally cylindrical body having an upper end portion for projecting above the jawbone and a lower stem portion for insertion in a recess prepared in a patient's jawbone;

the upper end portion having a central bore for insertion of a portion of a dental device to be attached to the implant member; and

the lower end portion having an outer cylindrical surface and a plurality of multiple lead threads projecting outwardly from the outer surface.

43. The implant member as claimed in claim **42**, wherein the upper end portion includes a cylindrical ring portion of diameter greater than said cylindrical surface of the lower end portion, and an inwardly tapered rim portion projecting upwardly from said ring portion.

44. The implant member as claimed in claim **43**, wherein said ring portion has a diameter equal to the diameter of said threads.

45. The implant member as claimed in claim **43**, wherein said upper end portion has a height less than that of the lower end portion.

* * * * *

US005427527A

United States Patent [19]

Niznick et al.

[11] Patent Number: 5,427,527

[45] Date of Patent: Jun. 27, 1995

[54] DENTAL IMPLANT METHOD OF INSTALLATION

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[73] Assignee: Vent Plant Corporation, Philadelphia, Pa.

[21] Appl. No.: 66,561

[22] Filed: May 25, 1993

[51] Int. Cl.[6] A61C 8/00

[52] U.S. Cl. 433/174

[58] Field of Search 433/173, 174

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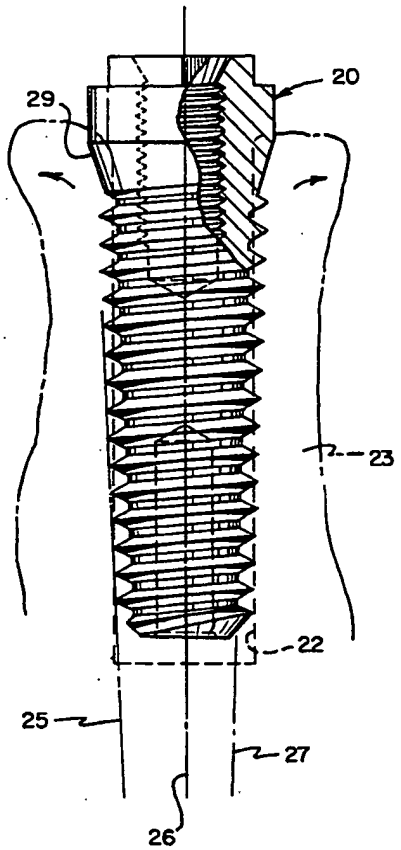
Primary Examiner—John J. Wilson

Attorney, Agent, or Firm—Darby & Darby

[57] ABSTRACT

A dental implant system utilizes a threaded implant which is cylindrical in form and has a large number of longitudinal channels so it can be (i) screwed into place in a bore hole in the patient's bone, (ii) pushed into place or (iii) first pushed into place and then turned to anchor it in bone ridges formed when it is pushed into place. Also an implant is given a conical shape it can be used for supporting artificial teeth in a residual ridge crest of a patient by drilling a smaller than normal cylindrical hole in the crest and carefully inserting the conical implant so that the bone is spread and makes additional contact with the implant.

3 Claims, 3 Drawing Sheets



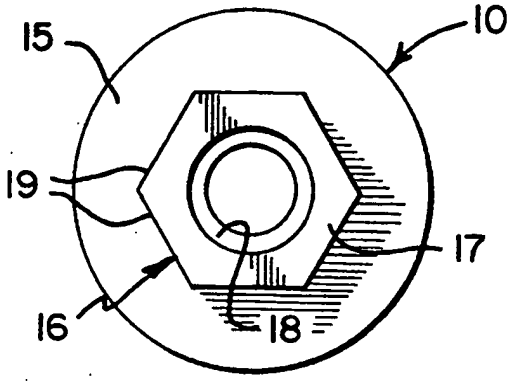


FIG. 1A
PRIOR ART

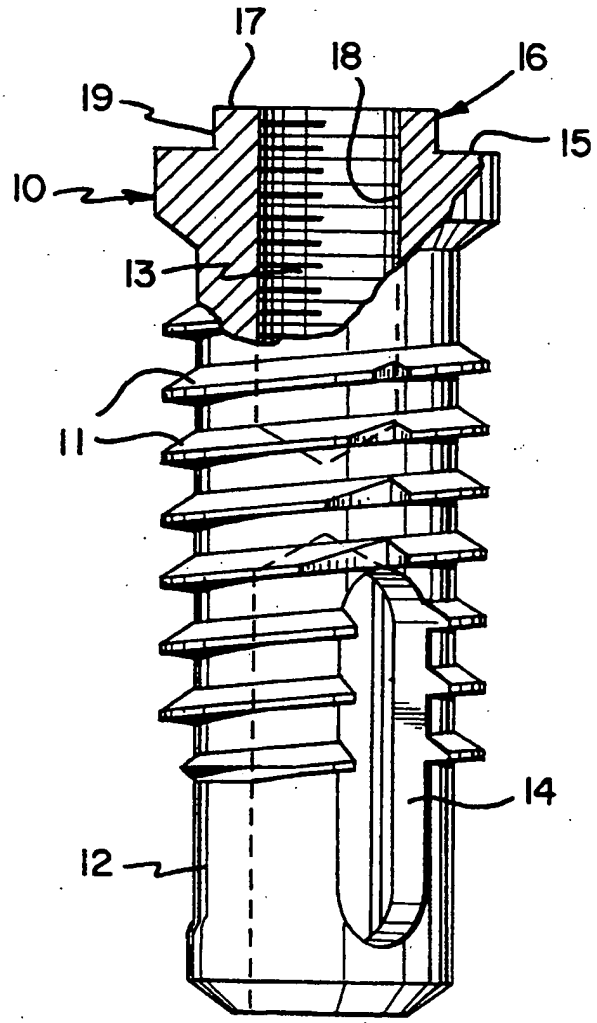


FIG. 1B
PRIOR ART

FIG. 2

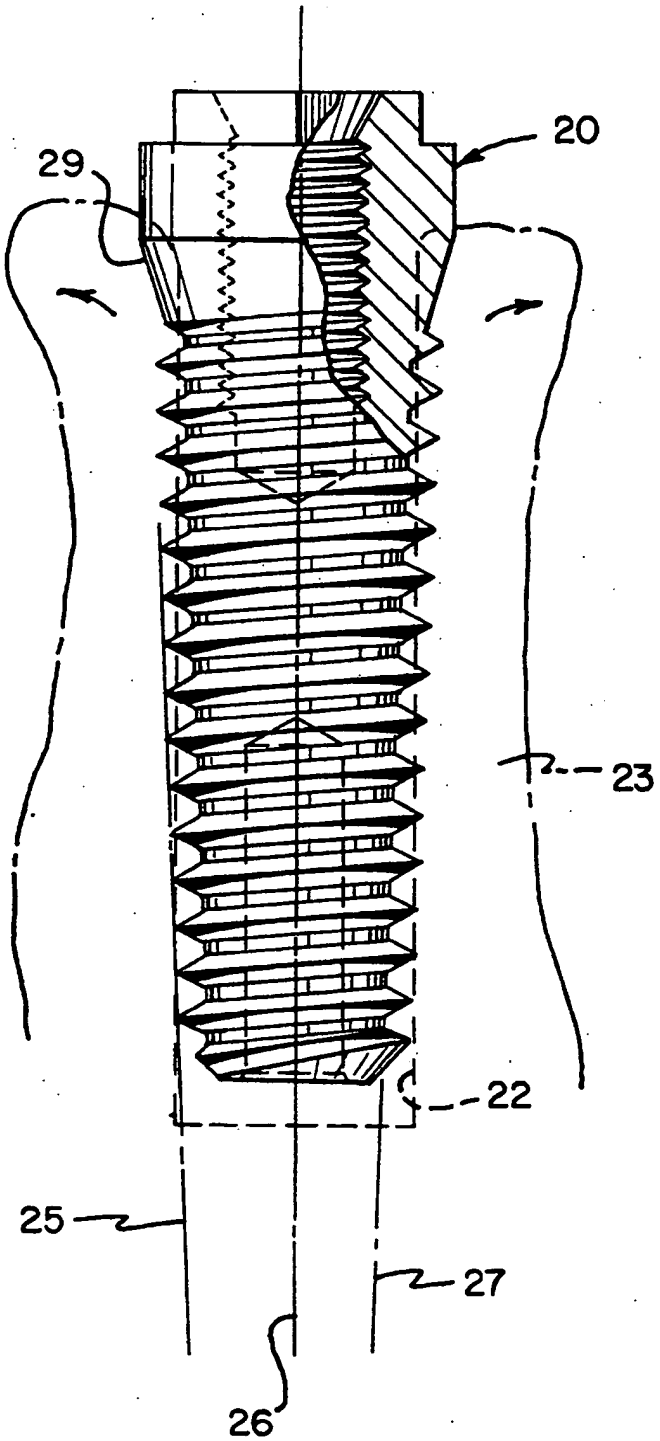


FIG. 3B

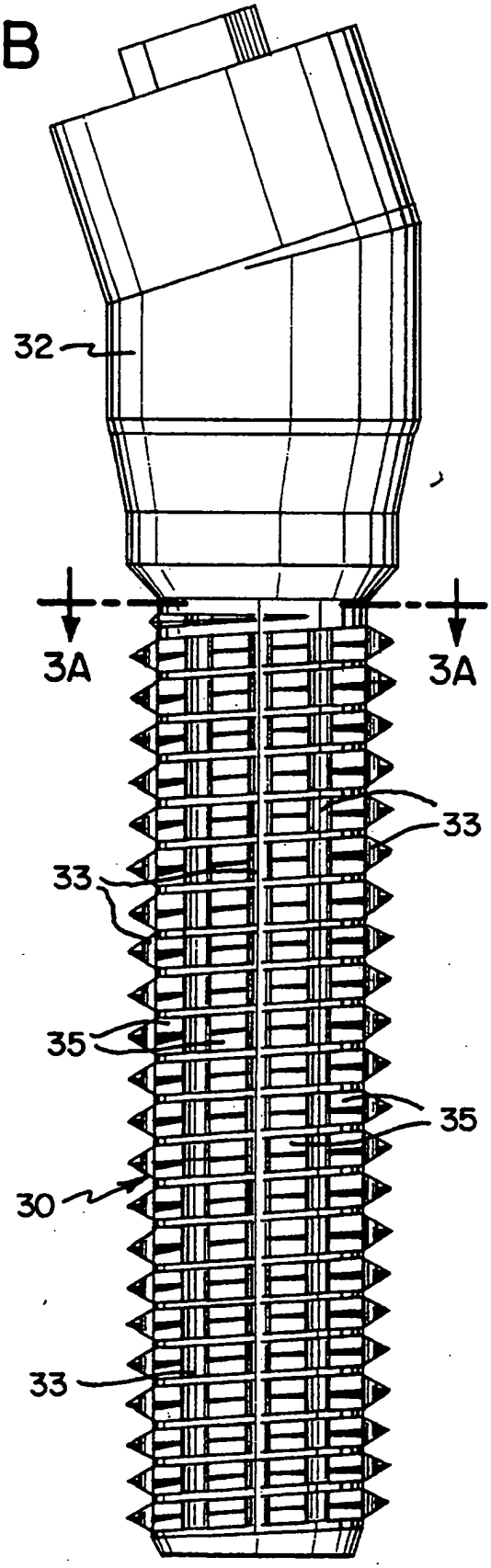
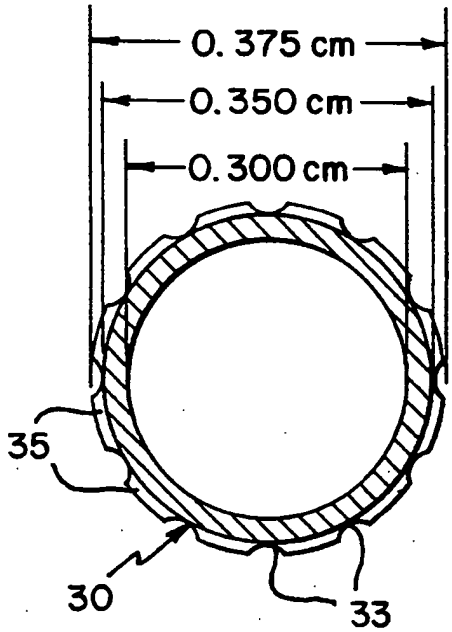


FIG. 3A



DENTAL IMPLANT METHOD OF INSTALLATION

TECHNICAL FIELD

This invention relates to dental implant devices and, more particularly, to screw-type dental implant systems.

BACKGROUND ART

Screw-type implants are now well-known. U.S. Pat. No. 3,499,222 of L. I. Linkow et al. discloses screw-type implants which may be buried in the alveolar ridge crest bone of a patient in an edentulous region. The implant has a threaded lower portion which may be screwed into an opening created in the bone after the tissue has been displaced. A coronal portion protrudes above the bone and is used to support an artificial dental appliance, e.g., an artificial tooth or bridge.

In more recent years, submergible implants have been created in which the threaded portions of the implants can be completely embedded in the bone. They may then be covered with tissue and allowed to remain in place while new bone grows around the implant and through vent holes within the implant. Once it is firmly anchored in new bone, the tissue is reopened and an abutment or upper post portion is screwed into the implant portion and is used to mount the artificial dental device. Submergible implants of this type are disclosed in U.S. Pat. No. 4,713,004 of Linkow et al.

It is advantageous, when installing an implant portion in the patient's jawbone, for the implant to self-tap into the bore hole created in the patient's jawbone because this causes the implant to be better anchored in the bone. As shown in U.S. Pat. No. 4,713,004 of Linkow et al, such an implant may include a cylindrical body with an exterior threaded region that contains a longitudinal channel through a portion of the outer parts of the threads. The channel is wider toward its bottom. One side of the channel is at a right angle to the implant circumference so as to create a cutting edge that creates a self-tapping capability for the implant when it is threaded into a bore or opening in the patient's bone. The channel guides bone chips, created during the threading of the implant, toward the base of the bore in the bone. The bone chips created during the self-tapping operation promote faster bone growth due to their autogenous nature.

The majority of submergible dental implants sold today have an external hexagonal head ("hex-head") which projects from the outer end and is used to couple the implant to an insertion device, e.g. a wrench. This projecting hex-head is also used in attaching the implant to an abutment or post having a matching hex-shaped cavity that receives the projection. Such projecting heads and cavities may be referred to as "coupling surfaces."

Certain areas of the jawbone, such as the thin ("bucco-lingual") residual ridges located primarily in the maxilla, are too thin to allow drilling with a cylindrical drill of The preferred size range in order to create the bore hole. This, in turn, leads to the use of narrower implants. However, due to the decreased surface area of bone contact and their small diameter, these narrower implants are much more likely to fail.

DISCLOSURE OF THE INVENTION

This invention relates to improvements in the implant portion of screw-type dental implants that are achieved by means of various designs of the implant portion that permit stable engagement with surrounding bone (e.g. a conical shape or a cylindrical shape with bone engaging threads or projections).

In an illustrative embodiment of the invention, the implant portion has relatively narrow threads and a plurality of channels spaced about the circumference of a cylindrical implant portion. As a result, the implant portion may be pushed into place in a bore hole created in the patient's alveolar ridge, instead of being screwed into place. Since the threads are narrow, and the bone is relatively soft, channels are gouged in the bone at the location of the threads, while ridges of bone are formed at the location of the channels. When installed, the bone ridges prevent accidental rotation of the implant. However, if desired, once the implant portion is fully inserted in the hole, it may be given a slight rotation, e.g. by means of a wrench applied to its projecting hex-head, so that the portions of thread between the longitudinal channels can cut into the ridges of bone to anchor the implant portion in place.

The present invention also contemplates conical implant portions inserted into cylindrical bore holes in narrow alveolar ridges. When inserted, the upper portion of the implant (which is somewhat too large for the bore hole) spreads the adjacent bone of the ridge, thus enlarging the amount of bone which can be used to anchor the implant. The upper part of the implant where most of the stress is concentrated is also larger. The increase in bone and implant contact surface area, and the size of the upper part of the implant due to the use of a conical shape, can be critical to the long-term stability of an implant inserted into a thin residual alveolar ridge.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the present invention will be more readily apparent from the following detailed description and drawings of illustrative embodiments of the invention, in which:

FIG. 1A is a top view of a typical prior art hex-head implant showing the surface which would couple to an abutment;

FIG. 1B is a side view of a prior art implant, with the hashed-line portions of the drawing representing a cross-sectional cut-away;

FIG. 2 shows a side view of a conical implant inserted in a residual alveolar ridge crest;

FIG. 3A shows a cross sectional view of a multi-channel threaded implant portion shown in FIG. 3B taken along the line 3A—3A; and

FIG. 3B shows a side view of the implant portion of FIG. 3A.

DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

FIGS. 1A and 1B illustrate a typical prior art implant portion **10**, with the hashed-line portions of the drawing representing a cross-sectional cut-away. The implant body **12** is generally cylindrical and its exterior sides will normally have threads **11**, which may be self-tapping to facilitate anchoring the implant in the bone. A vent hole **14** passes through body **12**. After the implant has been installed, bone may grow through the vent, thus further anchoring the implant.

FIG. 1A shows a top view of a typical external hexagonal projecting head **16** ("hex-head") which provides

the coupling surfaces of an implant portion that engage the coupling surfaces of an abutment. The hex-head coupling surfaces include a lower surface **15** which forms the base of the hex-head, an upper surface **17** which forms the cap of the hex-head and a threaded aperture **18** which extends through the hex-head and into the implant portion. In the side view of FIG. 1B the side walls **19** of the hex-head are shown along with the threads **13** of the aperture **18** for the abutment screw.

Thin (bucco-lingual) residual ridges located in, but not limited to, the maxilla, limit the width of cylindrical drills and implants that can be used. Therefore narrow implants of insufficient surface area have to be used, but these have a greater tendency to fail.

As shown in FIG. **2**, a conical implant **20** may be screwed into a smaller cylindrical hole **22** (shown in dotted line) in a residual ridge bone **23**. Due to the conical nature of the implant, the implant spreads the thin residual ridge as represented by the arrows in FIG. **2** and successfully engages a larger surface area implant. The spread bone should preferably be allowed to heal before the implant is put into active use by mounting an abutment on it. Conical implants were developed to be inserted into conical voids in bone of about the same size which are created by the extraction of natural teeth which have become diseased. Thus, the present invention represents a new use of such implants.

The conical implant of the present invention can be with or without a cutter channel mechanism, and with or without an external hex mechanism for attachment to an abutment. The angle of taper for the conical implant of FIG. **2** is illustrated by the angle between reference lines **25** and **26** or between reference lines **26** and **27**, which is about 2°.

With a 2° taper over a threaded portion of about 7.5 mm in length, as shown in FIG. **2**, the diameter of the bore hole is about 3.3 mm, the diameter of the implant at the top of the threads is about 3.6 mm and the diameter at the base surface of the contact area **29** of the implant it is about 4 mm. This shows that the implant is significantly stronger at its top portion than if it were the diameter of the bore hole over its entire length. The angle of taper for the conical implants of the invention is preferably between about 1° and about 10° , more preferably between about 1° and 3° (with the angle measured between the main axis of the implant **26** and the tapered surfaces **25, 27**). The entire length of the implant need not be conical as shown in FIG. **2**. Some portions may be cylindrical, so long as about 50% of the length is conical. In all cases, the upper portion of the implant (having the coupling surface **29**) will have the greater diameter.

The conical implants according to the invention may have any maximum diameter suitable for implants. However, it is anticipated that these implants will most often be used in the residual ridges. For this purpose, a maximum diameter of between about 3 mm and about 4 mm is preferred, with an overall length of about 10 mm.

FIGS. **3A** and **3B** illustrate cross-sectional and side views of a cylindrical threaded implant **30** with an angled abutment **32**. The threads of this implant are interrupted by a plurality of longitudinal channels **33**. As can be seen from the cross sectional view of FIG. **3A**, the channels are so numerous (i.e. **12** in FIG. **3A**) and closely spaced as to give a serrated appearance. In a typical embodiment the implant has an outer diameter for its threads of 0.375 cm. The diameter at the depth of the channels is 0.350 cm, while the inner diameter of the threads is 0.300 cm. Thus the channels in this illustrative embodiment are 12.5 mm deep. However, channels as deep as 25 mm are acceptable.

In one use for the implant of FIG. **3**, it is screwed into a bore hole in the jaw of a patient in a conventional manner. With this use the bore hole is made to have dimensions that approximate those of the inner diameter of the screw threads. In a second use, the implant is merely pushed into place in the bore hole. In this use, the bore hole has a diameter about equal to the diameter at the depth of the channels. During this procedure the sections **35** of the threads between the channels **33**, crush the surrounding bone to a slight extent as the implant is pushed into the hole. As a result, raised ridges of bone are created in the areas of the channels. These ridges prevent rotation of the implant. As another use, the implant is pushed into place and then, using a wrench over an external or internal hex, it is rotated slightly so the thread sections cut into the adjacent bone ridges to lock the implant in place more securely. As a result, the same implant can be used for three different insertion techniques. All that needs to be done to use these techniques is to adjust the size of the bore hole.

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. A method of mounting an implant in a thin residual alveolar ridge crest, comprising:

forming a cylindrical bore hole in the ridge crest that is of a size that it is well within the available bone;

introducing a conical threaded implant in to the bore hole in the patient's ridge crest, a lower part of the implant being smaller in diameter than the bore hole and an upper part of the implant being greater in diameter than the bore hole;

installing said implant into said bore hole such that said installation causes the upper part of the implant to spread the bone about the bore hole, and

after the implant is fully installed, allowing a period of time to pass sufficient for the spread bone to heal.

2. The method of claim **1**, wherein the taper of said conical implant ranges from about 1° to about 10°.

3. The method of claim **2**, wherein the taper is about 2°.

* * * * *

US005527183A

United States Patent [19]

O'Brien

[11] Patent Number: 5,527,183

[45] Date of Patent: Jun. 18, 1996

[54] ENDOSSEOUS IMPLANT SYSTEM

[75] Inventor: Gary O'Brien, Glendale, Calif.

[73] Assignee: Collaborative Enterprises, Inc., Glendale, Calif.

[21] Appl. No.: 288,278

[22] Filed: Aug. 9, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 108,869, Aug. 18, 1993, Pat. No. 5,435,723.

[51] Int. Cl.[6] A61C 8/00

[52] U.S. Cl. 433/174; 433/173

[58] Field of Search 433/172, 173, 433/174, 175, 176

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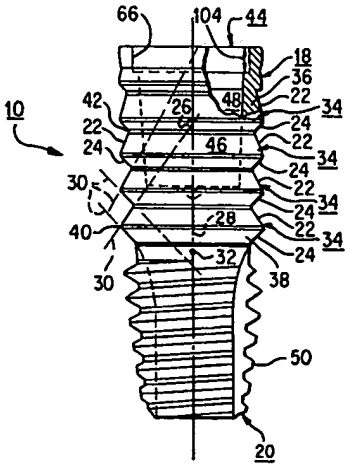
Primary Examiner—Cary E. O'Connor

Attorney, Agent, or Firm—Morton J. Rosenberg; David I. Klein

[57] ABSTRACT

An endosseous implant body for affixing an orthopedic prosthesis into bone is provided. The implant body generally has at least four segments disposed proximate to a coronal end of the implant body. Each segment consists of a frustro-conical compression moiety and a frustro-conical tension moiety. The angles of incidence and the surface areas of the compression moieties are chosen so that, when the body is implanted into bone and a lateral force is applied to the coronal end of the body, that portion of the lateral force which is exerted by the compression moiety of each segment against the surrounding bone is greater than that portion of the lateral force which is exerted by the compression moiety of an adjacent segment disposed more proximate to the coronal end. Likewise, the angles of incidence and the surface areas of the tension moieties are chosen so that, when the body is implanted into bone and a lateral force is applied to the coronal end of the body, that portion of the lateral force which is exerted by the tension moiety of each segment against the surrounding bone is less than that portion of the lateral force which is exerted by the tension moiety of an adjacent segment disposed more proximate to the coronal end. The implant body of the invention has been found to produce a stable implant sight for orthopedic prostheses, especially dental prostheses. The design of the implant body results in a much more even distribution of occlusal forces to the prosthesis, thereby minimizing degradation of the implant sight over time. Additionally, the invention employs a new prosthetic connection in which one or both components (the body and prosthesis attachment structure) contain a Mores taper which locks the attachment structure to the body of the implant when properly attached. The assembly may also be designated with multiple orientations or only one orientation circumferentially.

21 Claims, 12 Drawing Sheets



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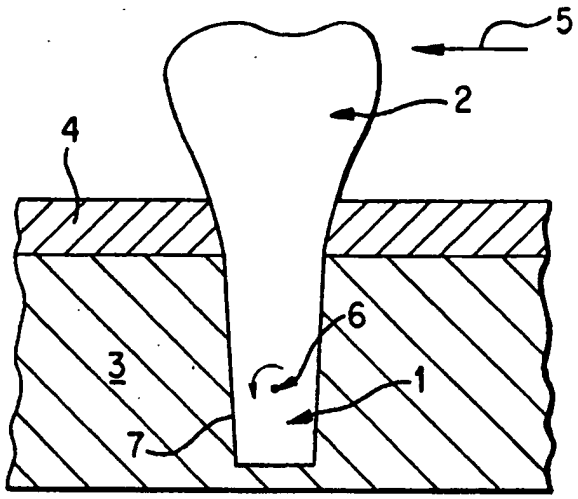

FIG. 1
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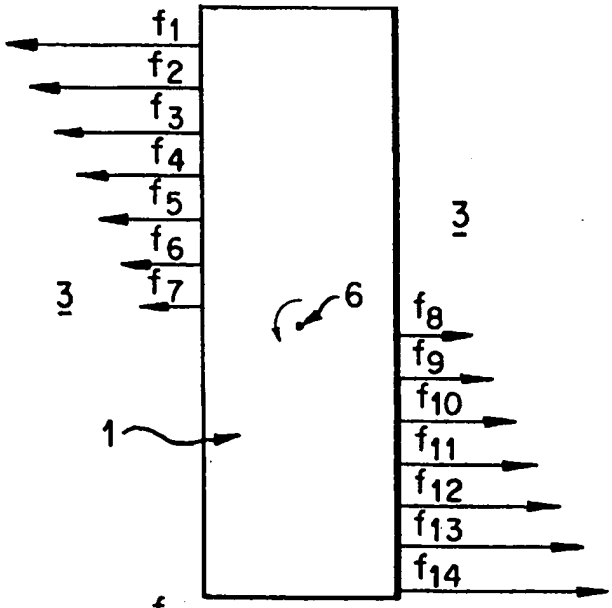
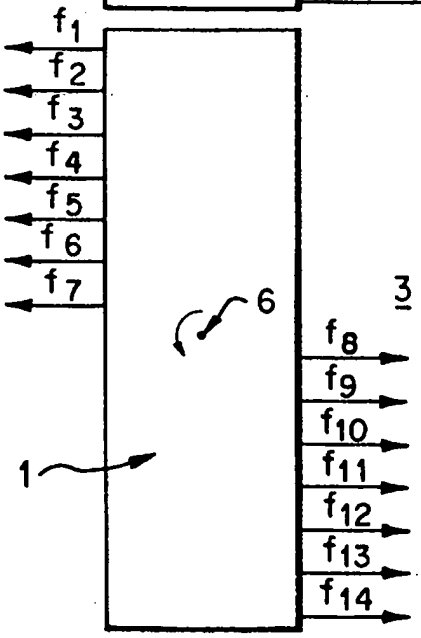


FIG. 2
PRIOR ART



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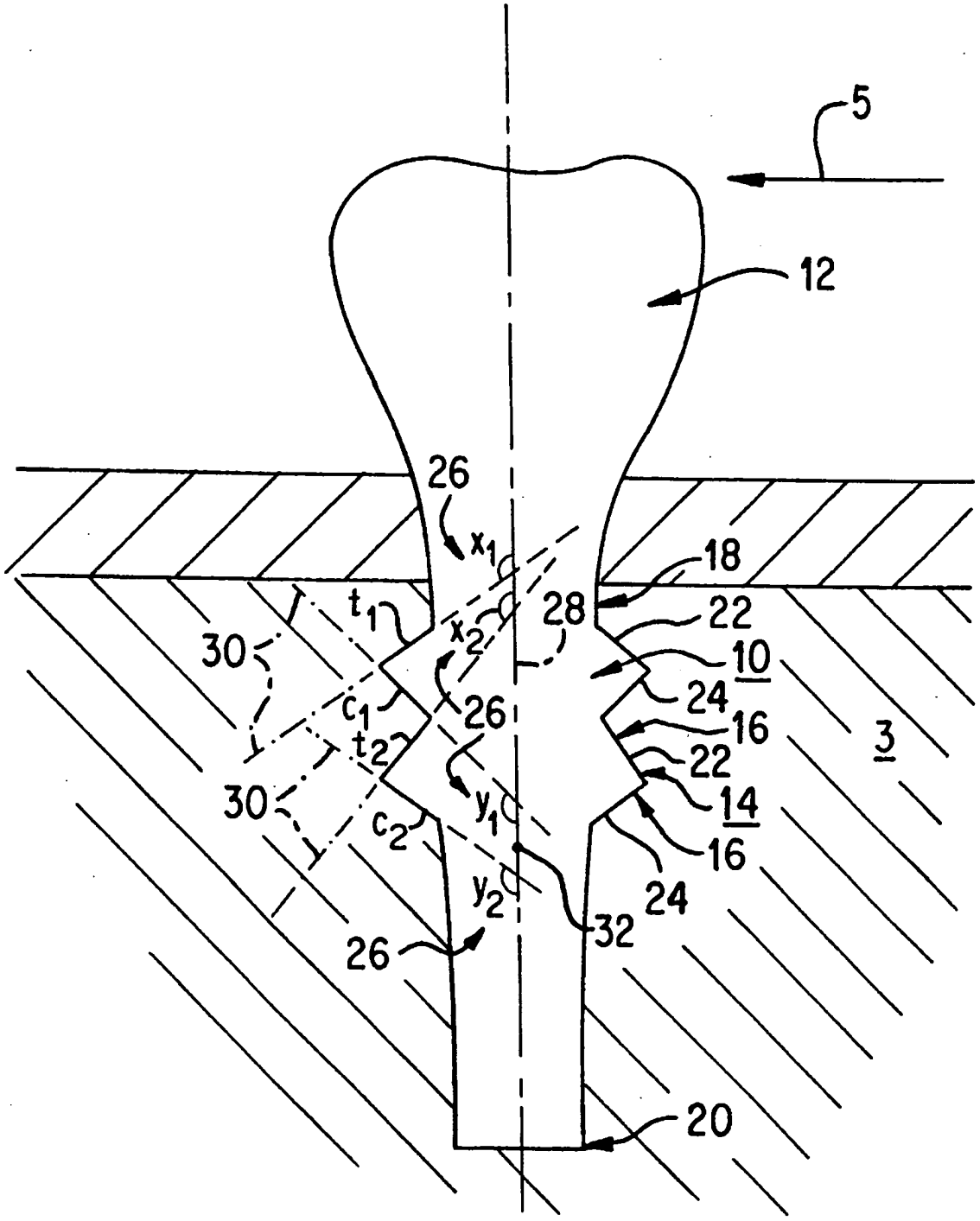
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x_2
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26
20

FIG. 4

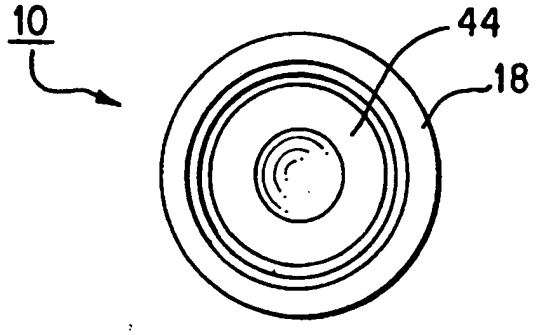


FIG. 6

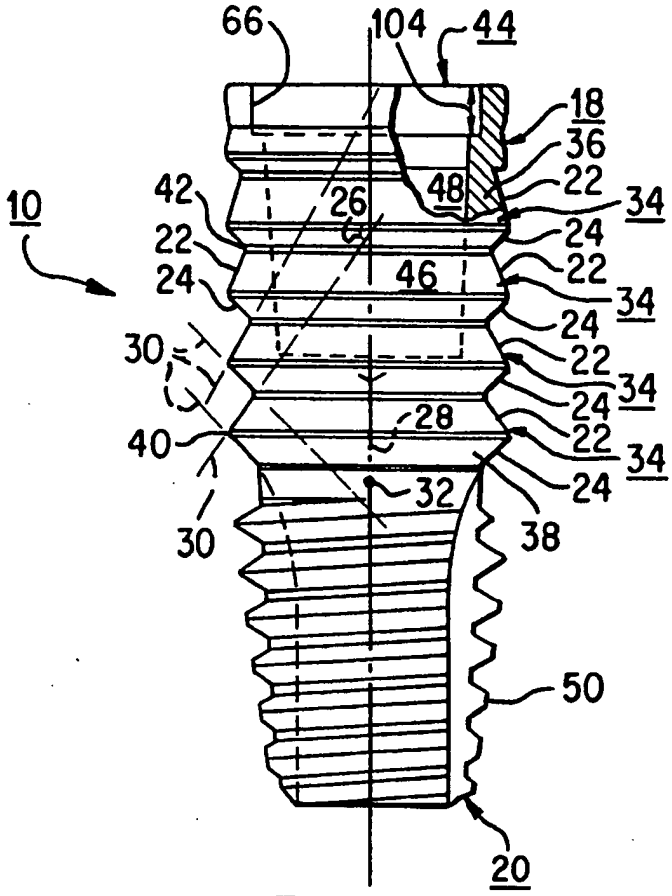


FIG. 5

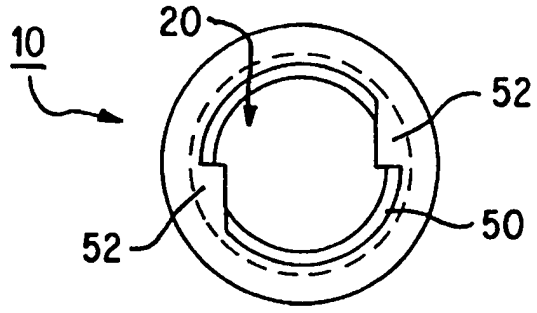


FIG. 7

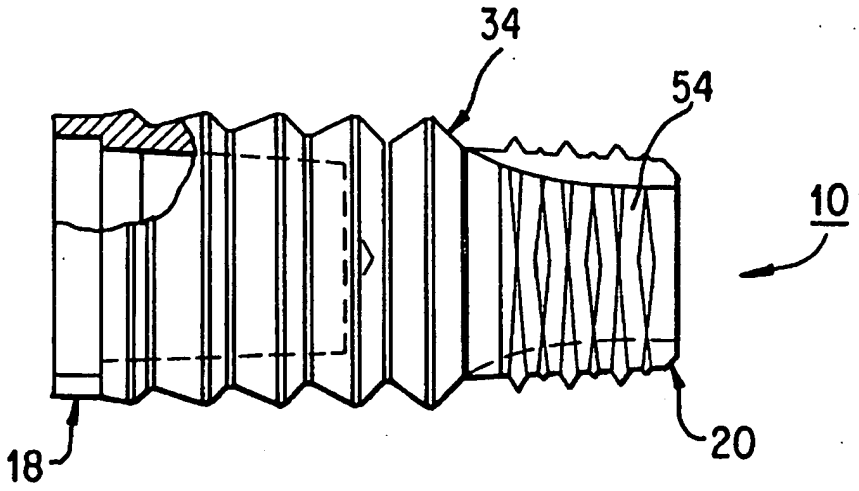


FIG. 8A

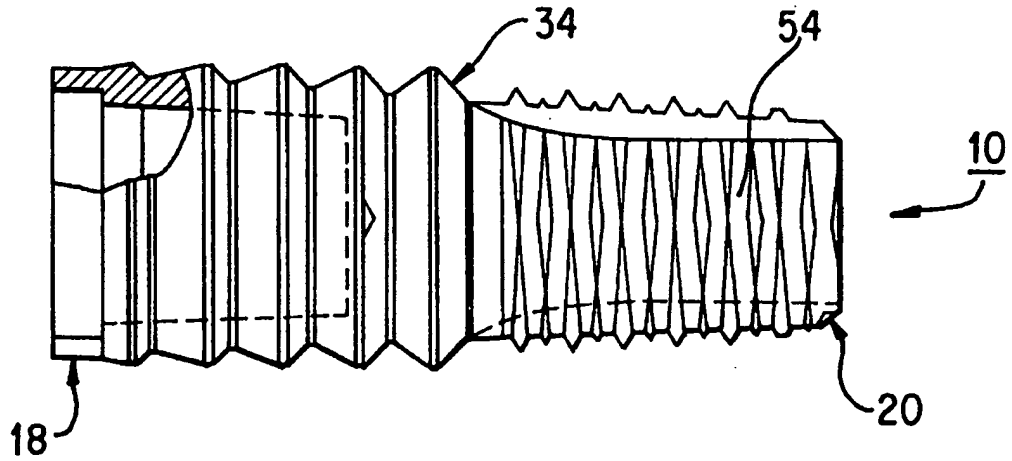


FIG. 8B

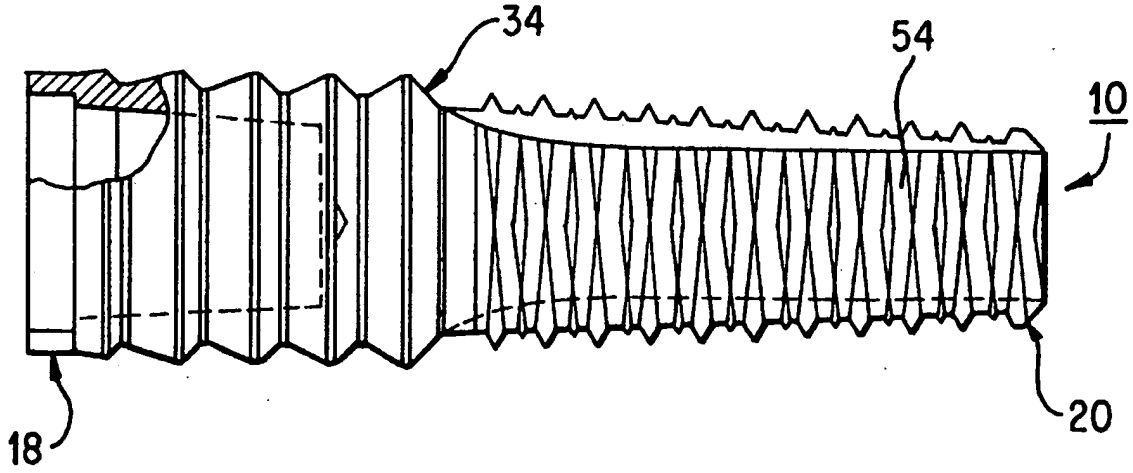


FIG. 8C

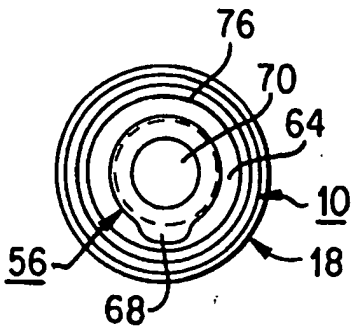


FIG. 14

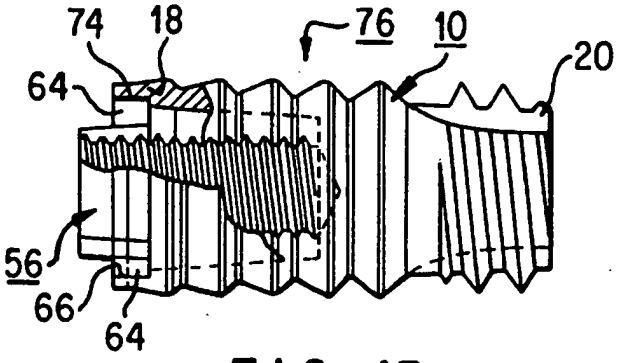


FIG. 13

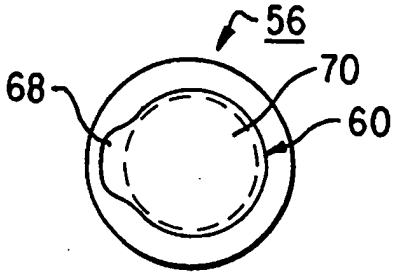


FIG. 10

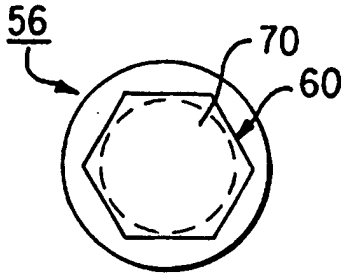


FIG. 12

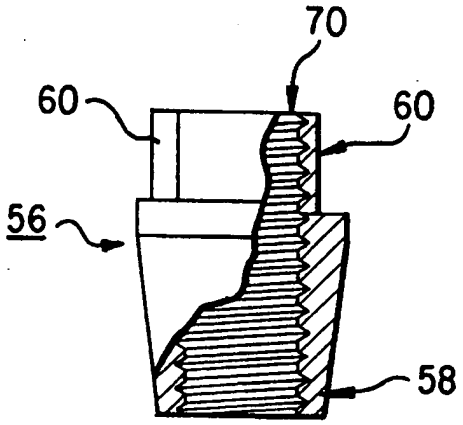


FIG. 9

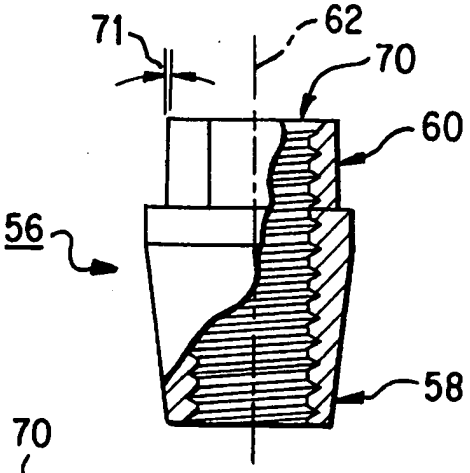


FIG. 11

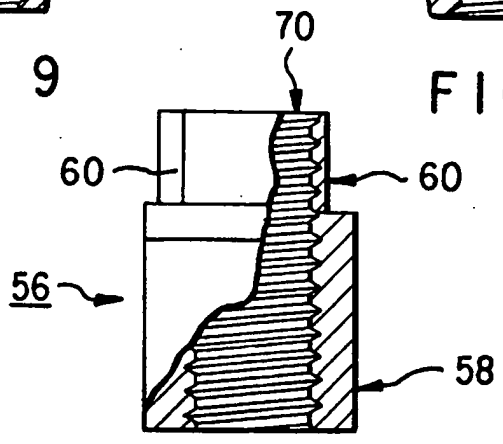


FIG. 9A

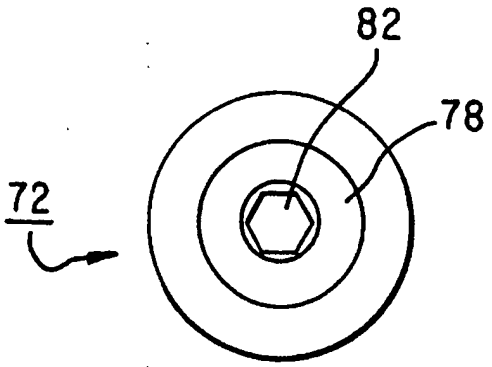
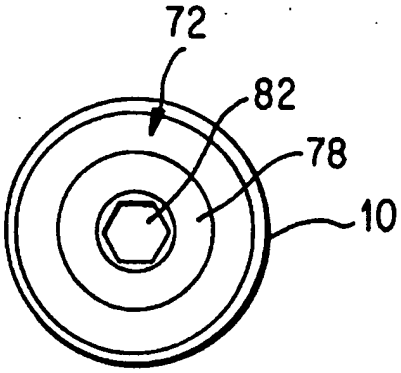


FIG. 17



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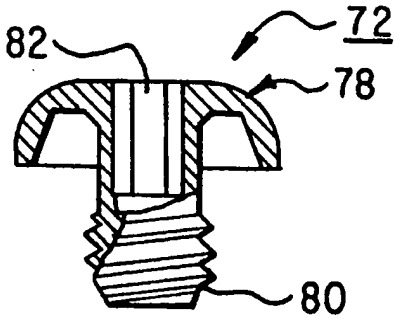


FIG. 15

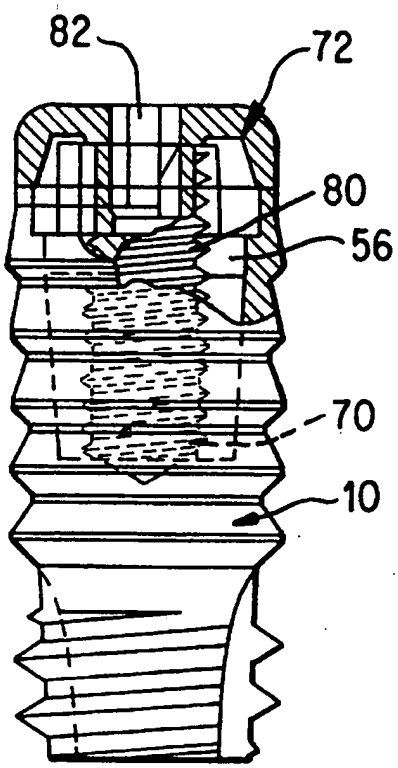
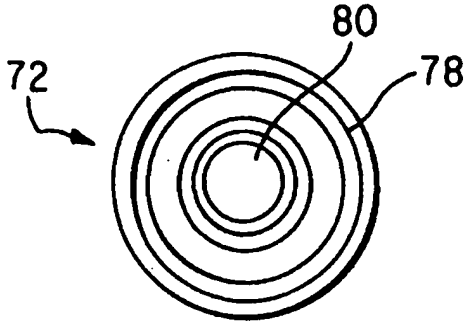


FIG. 18



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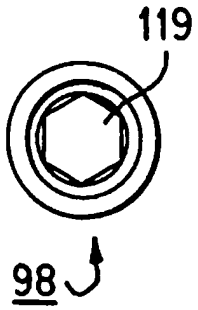

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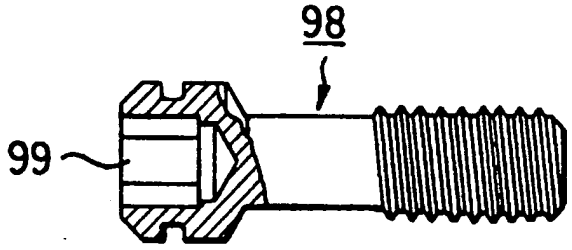

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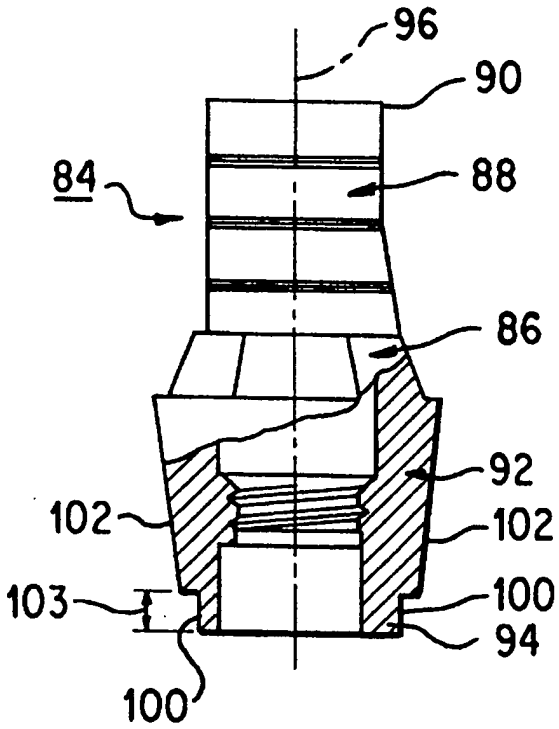
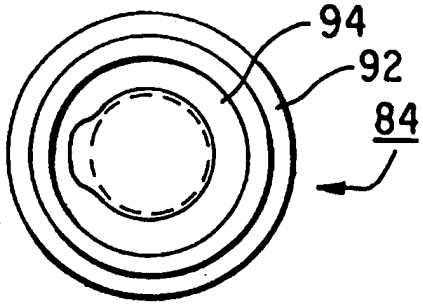


FIG. 20



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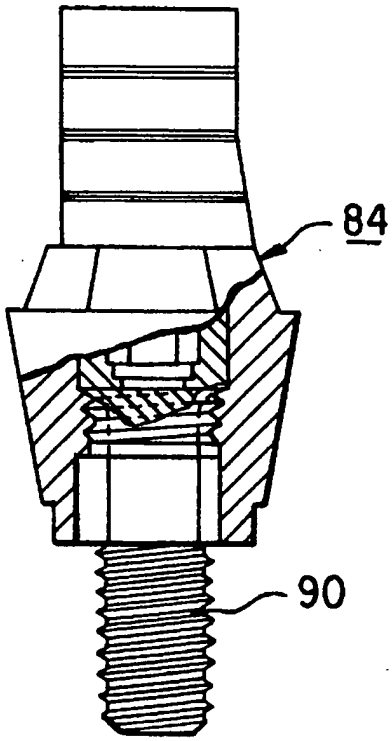


FIG. 24

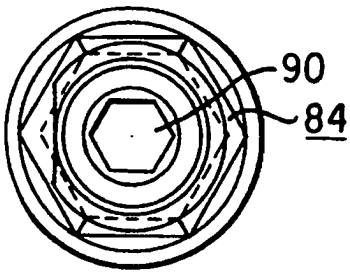
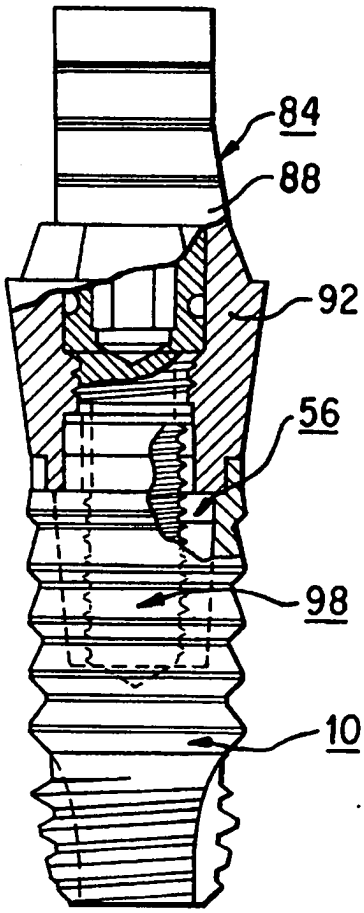


FIG. 26



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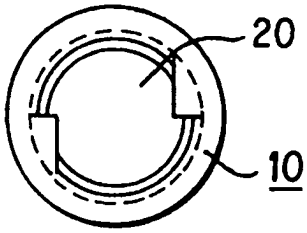


FIG. 27

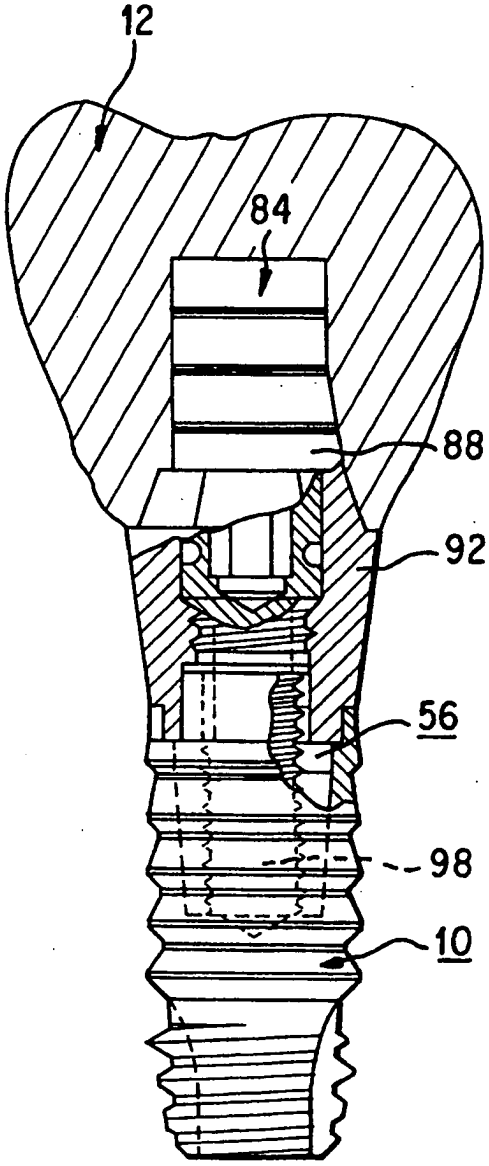


FIG. 28

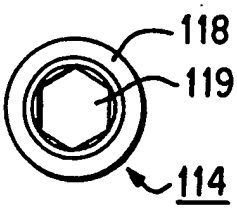
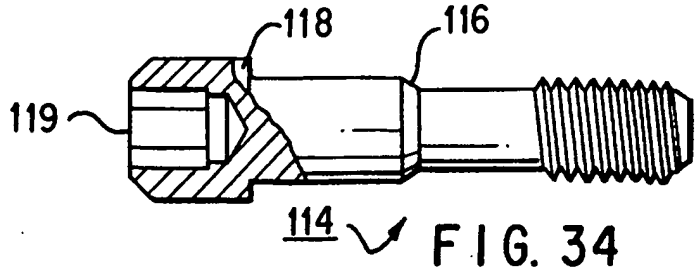


FIG. 35



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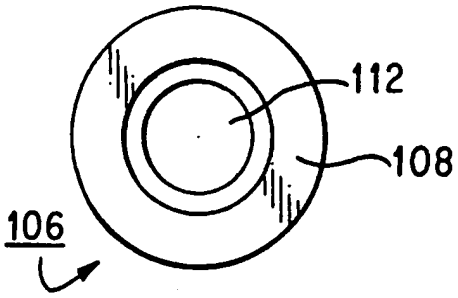

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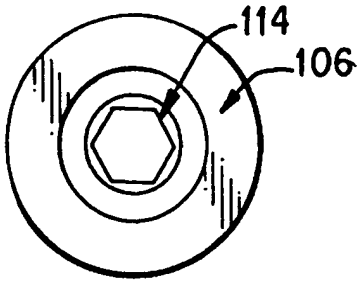

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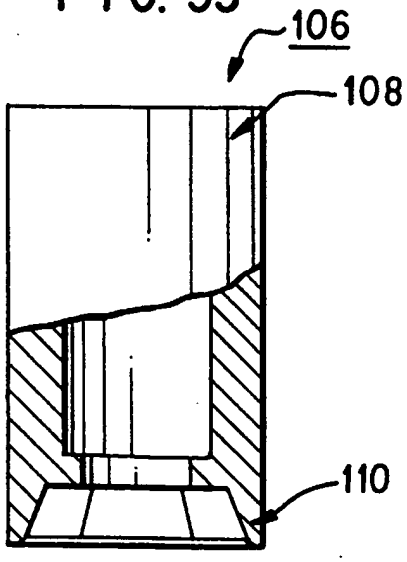

FIG. 31

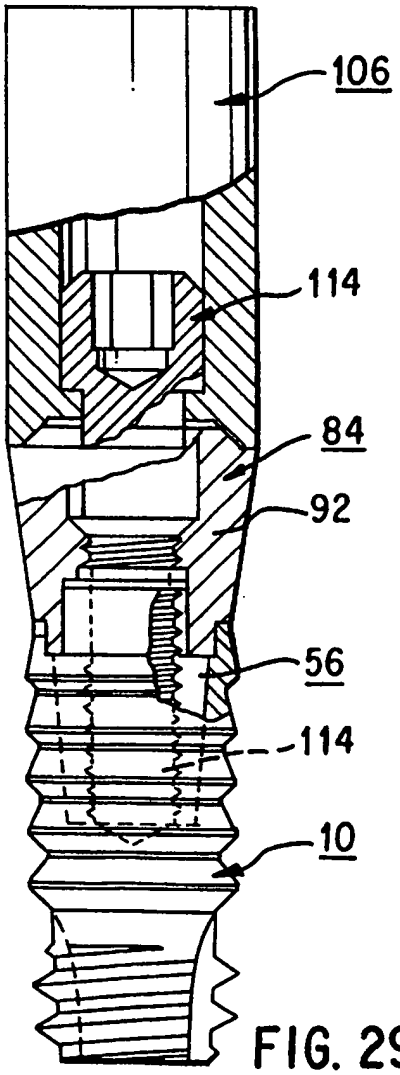

FIG. 29

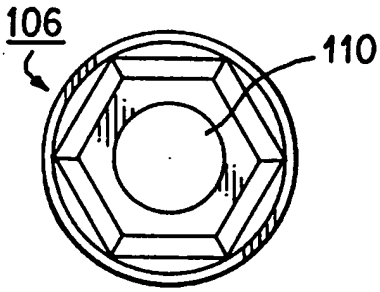

FIG. 32

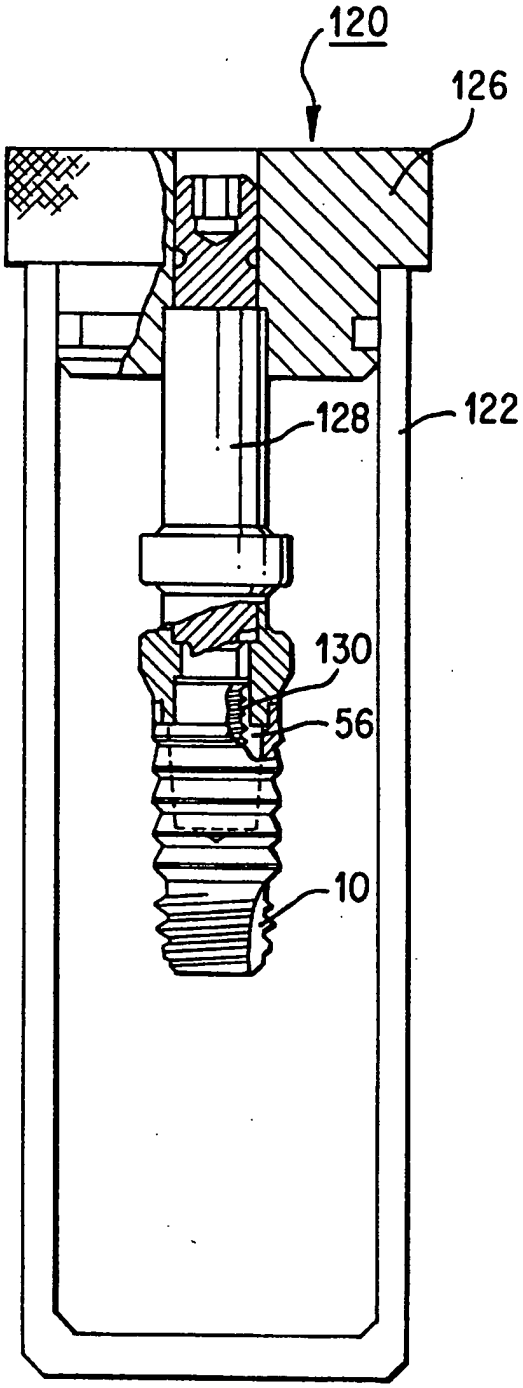

FIG. 36

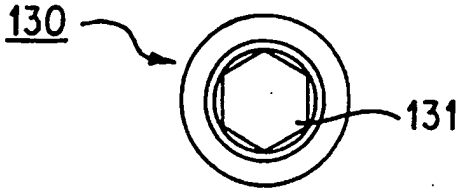

FIG. 38

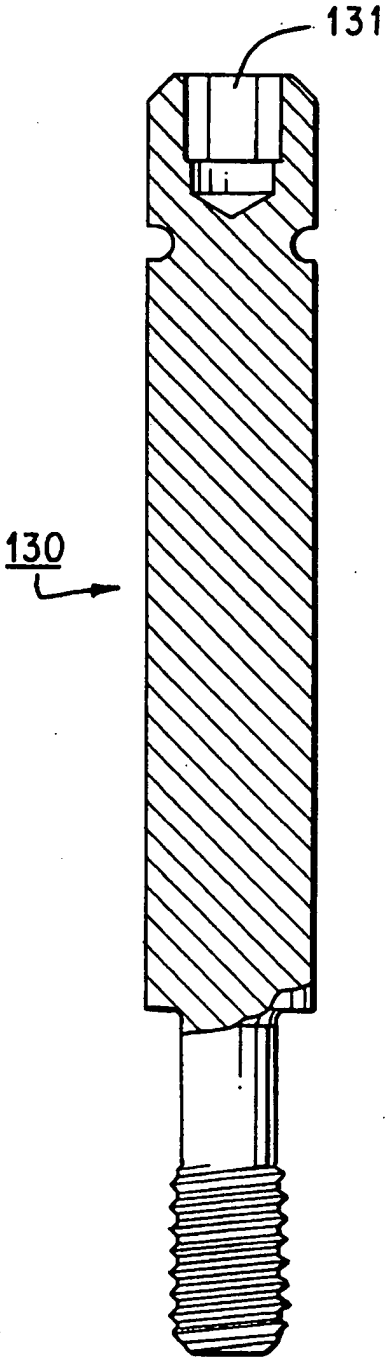

FIG. 37

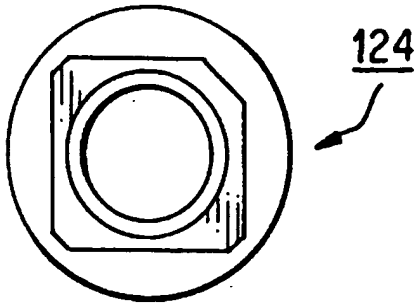

FIG. 41

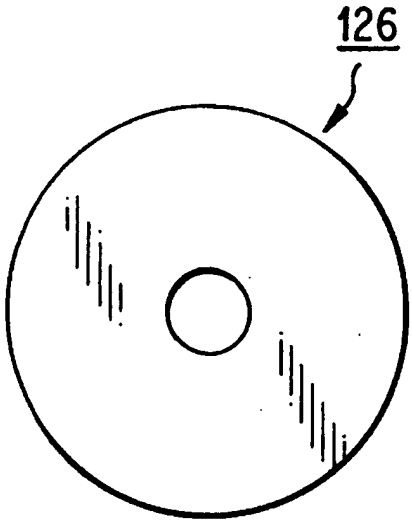

FIG. 44

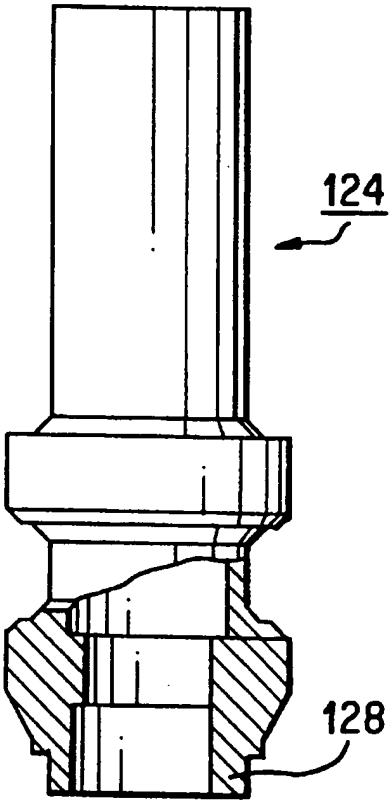

FIG. 39

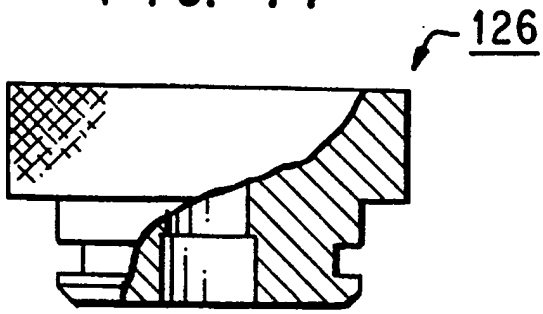

FIG. 42

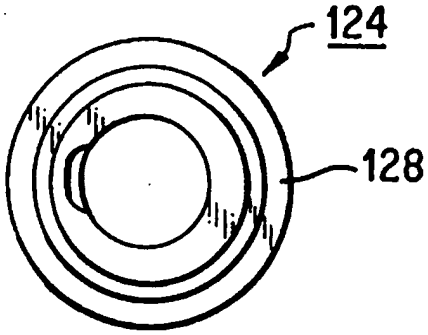

FIG. 40

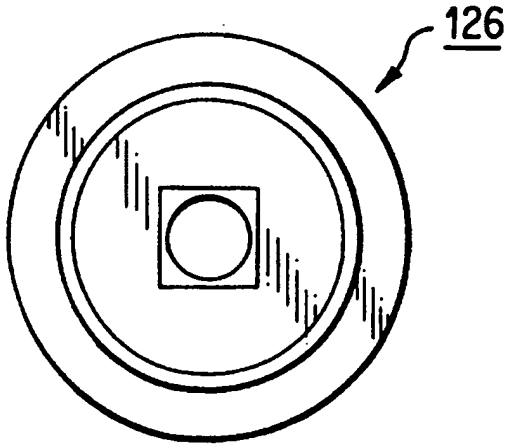

FIG. 43

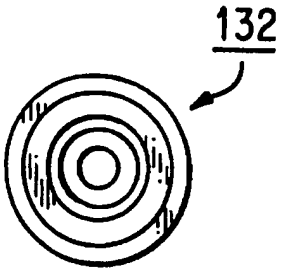

FIG. 46

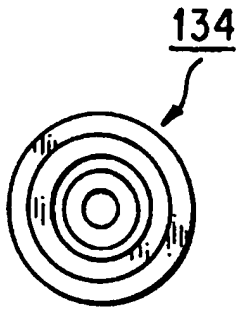

FIG. 49

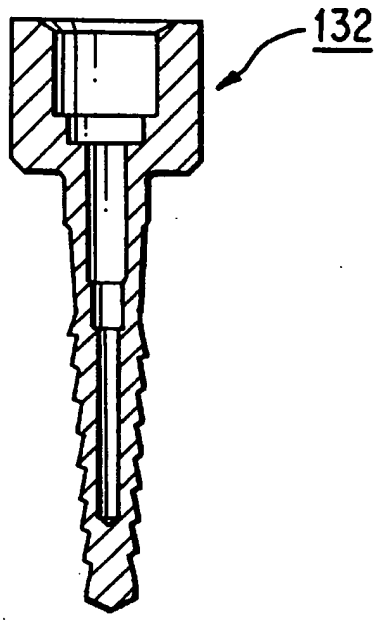

FIG. 45

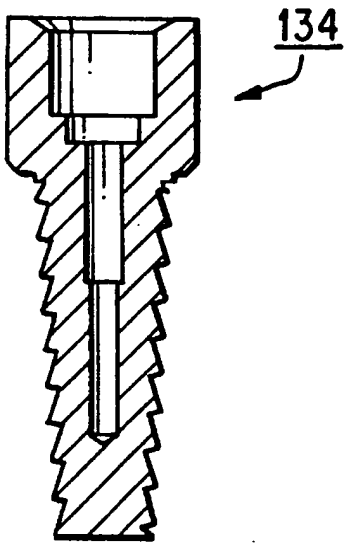

FIG. 48

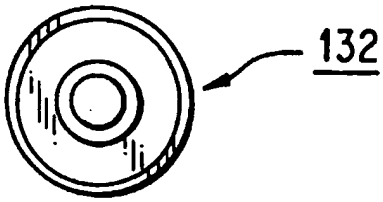

FIG. 47

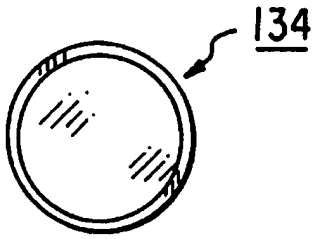

FIG. 50

ENDOSSEOUS IMPLANT SYSTEM

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 08/108,869, filed Aug. 18, 1993, now U.S. Pat. No. 5,435,723.

FIELD OF THE INVENTION

This invention relates generally to artificial orthopedic implant prostheses, and particularly, but not exclusively, to dental implant prostheses.

BACKGROUND OF THE INVENTION

The installation of an orthopedic prosthesis, whether it be a dental prosthesis such as bridge work or other bone implant prosthesis such as an artificial limb, requires affixing the prosthesis to one of the patient's bones. Generally, this is accomplished by first affixing a metallic implant connection member into the connector bone and then affixing the prosthesis to the implant connection member.

A fundamental problem with the installation of orthopedic prostheses is the tendency of the bone installation sight to "wear out" over time. This resorption of bone ("wear out") is characteristically seen after load is introduced. Clinical evidence of this destruction begins at the coronal aspect and moves progressively towards the apical end of the fixture creating a uniform saucerization. The fundamental problem is the inability of prior art implant systems to evenly distribute occlusal loads along the length of the implant connection member. This results in uneven stress to the bone immediately surrounding the implant connection member, and leads to eventual break-down of the implant sight. This problem is particularly acute with respect to dental implants, but it is also a common problem with respect to other orthopedic implants.

Therefore, there is a need for an endosseous implant system wherein the implant member is capable of more evenly distributing occlusal loads along the entire length of the implant connection member.

SUMMARY OF THE INVENTION

The invention satisfies this need. The invention is an endosseous implant body for implantation into bone. The implant body has a coronal end, a distal end and a plurality of segments proximate to the coronal end.

Each segment has a circular cross-section perpendicular to the longitudinal axis of the implant body and comprises a frustro-conical compression moiety and a frustro-conical tension moiety. As used herein, the term "tension moiety" means the coronal-side portion of the segment whose surface area generally faces in the direction of the coronal end of the implant body. Conversely, the term "compression moiety" as used herein means the distal-side portion of the segment whose surface area generally faces towards the distal end of the implant body.

Within each segment, both the compression moiety and the tension moiety have a maximum diameter, a minimum diameter and a substantially flat surface area disposed therebetween at an angle of incidence with respect to the longitudinal axis of the implant body. The angle of incidence is the obtuse angle formed by the intersection of the longitudinal axis of the implant body and a line drawn tangent to the flat surface area of one of the moieties.

The compression moiety is joined "back-to-back" with the tension moiety along each moiety's respective maximum diameter. The minimum diameter of each compression moiety is identical to and is attached to the minimum diameter of a tension moiety of an adjacent segment, if any.

The angles of incidence of all segment moieties and the surface areas of all segment moieties are chosen so that, when the implant body is implanted into bone and a lateral force is applied to the coronal end of the body, that portion of the lateral force which is exerted by the compression moiety of each segment against the surrounding bone is greater than that portion of the lateral force which is exerted by the compression moiety of an adjacent segment disposed more proximate to the coronal end.

Likewise, the angles of incidence and the surface areas of each of the tension moieties are chosen so that, when the body is implanted into bone and a lateral force is applied to the coronal end of the body, that portion of the lateral force which is exerted by the tension moiety of each segment against the surrounding bone is less than that portion of the lateral force which is exerted by the tension moiety of an adjacent segment disposed more proximate to the coronal end.

In one embodiment, the width of each compression moiety surface is greater than the width of the compression moiety surface of an adjacent segment disposed more proximate to the distal end. In this embodiment, the width of each tension moiety surface is generally chosen so as to be greater than the width of the tension moiety surface of an adjacent segment disposed more proximate to the coronal end.

Alternatively, the angle of incidence of each compression moiety surface can be chosen so as to be greater than the angle of incidence of the compression moiety surface of the compression moiety disposed more proximate to the distal end. In this embodiment, the angle of incidence of each compression moiety surface is generally chosen so that the angle of incidence of any one compression moiety surface is greater than the angle of incidence of the compression moiety surface disposed more proximate to the coronal end.

The invention is also a combination of an implant body having a coronal end bore and a plug disposed within the coronal end bore. The plug has a coronal end adapted for attachment to a prosthesis attachment member. The coronal end of the plug has at least one non-circular cross-section so that it attaches to the prosthesis attachment member in one and only one position. The plug may also be in the form of a tapered external hex or spline or slot.

The invention is also an implant delivery system comprising the combination described immediately above and an implanting tool. Such an implant system can be conveniently used to install the implant combination described above.

DESCRIPTION OF DRAWINGS

These and other features, aspects and advantages of the present invention will become better understood with reference to the following description, appended claims and accompanying drawings where:

FIG. **1** is a diagrammatic representation of a lateral force exerted on an endosseous prosthesis implanted into bone;

FIG. **2** is a force diagram showing typical forces imposed upon the endosseous implant of FIG. **1**;

FIG. **3** is a force diagram showing ideal forces imposed upon the endosseous implant of FIG. **1**;

FIG. 4 is a diagrammatic representation of a lateral force exerted on an endosseous prosthesis having features of the invention implanted into bone;

FIG. 5 is a side view of an implant body having features of the invention;

FIG. 6 is the coronal end view of the implant body shown in FIG. 5;

FIG. 7 is the distal end view of the implant body of FIG. 5;

FIG. 8 is a side view of three implant bodies having features of the invention, including knurled distal ends;

FIG. 9 is a side view in partial cross-section of a plug having features of the invention;

FIG. 9A is a side view in partial cross-section of an alternative plug which is non-tapered;

FIG. 10 is a coronal view of the plug of FIG. 9;

FIG. 11 is a second embodiment of a plug having features of the invention;

FIG. 12 is a coronal view of the plug of FIG. 11 with the external tapered hex design option;

FIG. 13 is a side view in partial cross-section of an implant combination having features of the invention;

FIG. 14 is a coronal view of the combination shown in FIG. 13;

FIG. 15 is a side view in partial cross-section of a healing cap useful in the invention;

FIG. 16 is a distal end view of the healing cap of FIG. 15;

FIG. 17 is a coronal end view of the healing cap of FIG. 15;

FIG. 18 is a side view in partial cross-section of the combination of an implant body-plug and healing cap having features of the invention;

FIG. 19 is a coronal end view of the combination of FIG. 18;

FIG. 20 is a side view in partial cross-section of an attachment structure having features of the invention;

FIG. 21 is a distal end view of the attachment structure of FIG. 20;

FIG. 22 is a side view in partial cross-section of a screw useful in the attachment of the attachment structure of FIG. 20;

FIG. 23 is a coronal end view of the screw illustrated in FIG. 22;

FIG. 24 is a side view in partial cross-section of a combination of the attachment structure of FIG. 20 and the screw of FIG. 22.

FIG. 25 is a side view in partial cross-section of another implant combination having features of the invention;

FIG. 26 is a coronal end view of the combination of FIG. 20;

FIG. 27 is a distal end view of the combination of FIG. 20;

FIG. 28 is a side view in partial cross-section of a further combination having features of the invention;

FIG. 29 is a side view in partial cross-section of a combination having features of the invention, including a cover sheath;

FIG. 30 is a coronal end of the combination of FIG. 29;

FIG. 31 is a side view in partial cross-section of a sheath useable in the combination of FIG. 29;

FIG. 32 is a coronal end view of the sheath of FIG. 31;

FIG. 33 is a distal end view of the sheath of FIG. 31;

FIG. 34 is a side view in partial cross-section of a screw useful in the combination of FIG. 29;

FIG. 35 is a coronal end view of the screw of FIG. 34;

FIG. 36 is a side view in partial cross-section of an endosseous implant delivery system having features of the invention;

FIG. 37 is a side view in partial cross-section of a screw useful in the delivery system of FIG. 36;

FIG. 38 is a coronal end view of the screw of FIG. 37;

FIG. 39 is a side view in partial cross-section of a tool shank useful in the delivery system of FIG. 36;

FIG. 40 is a distal end view of the tool shank of FIG. 39;

FIG. 41 is a coronal end view of the shank of FIG. 39;

FIG. 42 is a tool handle useful in the delivery system of FIG. 36;

FIG. 43 is a distal end view of the handle of FIG. 42;

FIG. 44 is a coronal end view of the handle of FIG. 42;

FIG. 45 is a side view in partial cross-section of a pilot drill useful in the invention;

FIG. 46 is a coronal end view of the pilot drill of FIG. 45;

FIG. 47 is a distal end view of the pilot drill of FIG. 45;

FIG. 48 is a side view in partial cross-section of a drill useful in the invention as the final sizing drill prior to insertion;

FIG. 49 is a coronal end view of the drill of FIG. 48; and

FIG. 50 is a distal end view of the drill of FIG. 48.

DETAILED DESCRIPTION OF THE INVENTION

The invention will be described by using specific language with reference to the accompanying illustrated embodiments. Although much of this description is directed to dental implants, it is understood that the scope of the invention includes other orthopedic implants and any modifications or alterations which would be obvious to those skilled in the art.

FIG. 1 illustrates a typical prior art endosseous dental implant body 1 and prosthesis 2 implanted into a patient's jawbone 3 below the gum line 4. When a lateral force 5 is applied to such a typical dental implant 1, that lateral force 5 tends to rotate the implant 1 about a certain point in the implant 1, which will be referred to herein as the "centroid 6." The location of the centroid 6 depends on the design of the implant 1. The lateral force 5 generates stress forces f_i within the jawbone 3 as illustrated by the force diagram shown in FIG. 2. As can be seen from FIG. 2, with prior art implant bodies the stress forces f_i placed upon the adjacent bone 3 furthest from the centroid 6 are much greater than the stress forces placed upon the bone 3 near the centroid 6. The excessive stress forces f_i placed upon the bone 3 adjacent to the implant body 1 furthest from the centroid 6 frequently results in degradation of that bone 3 over time.

What would be ideal would be an endosseous implant body which, when a lateral force is applied to the implant body, would evenly distribute the stress forces f_i applied to the bone adjacent to the implant body. Such an ideal stress force distribution is illustrated in FIG. 3. It is the principal object of the present invention to provide an endosseous implant body which will more closely approximate the stress forces illustrated in FIG. 3 (rather than the stress forces associated with prior art implants, as illustrated in FIG. 2).

The stress force diagram illustrated in FIG. 2 arises typically from an implant body 1 having a substantially

cylindrical shape with "straight" sidewalls **7**. Because the sidewalls **7** are "straight," and generally vertical with respect to the lateral force **5** applied to the prosthesis **2**, the resultant stress forces f_i applied to adjacent bone **3** at any particular location along the length of one side **7** of the implant body **1** differ only from the stress forces f_i applied to bone at another location by the distance between the location and the centroid **6** of the implant body **1**. Thus, a force diagram similar to FIG. **2** will always result from lateral forces **5** applied to implant bodies **1** having "straight" sides **7**.

Consider now the endosseous implant body **10** and prosthesis **12** illustrated in FIG. **4**. Note that the implant body **10** of FIG. **4** does not have "straight" sides. Rather the sides **14** have surfaces **16** of two different types: (1) surfaces which generally face the coronal end **18** of the implant body **10**, and (2) surfaces which generally face the distal end **20** of the implant body **10**. It can be mathematically shown that the surfaces facing the coronal end **18** of the implant body **10** (which shall herein be referred to as "tension surfaces **22**") generally exert less stress on bone **3** adjacent to the implant body **10** than do surfaces generally facing perpendicular to the implant body **10** (as in prior art implant bodies with "straight sides"). Also, it can be mathematically shown that the surfaces facing the base of the implant body (herein referred to as "compression surfaces **24**") generally exert greater stress on bone **3** adjacent to the impact body **10** than do surfaces generally facing perpendicular to the implant body **10**. Still further, it can be mathematically shown that between any two otherwise identical tension surfaces **22** or any two otherwise identical compression surfaces **24**, the surface having the greater surface area and/or the surface having the greatest "angle of incidence **26**" will exert the greater stress on bone **3** adjacent to the implant body **10**. As illustrated in FIG. **4**, the "angle of incidence **26**" is herein defined as the obtuse angle resulting from the intersection of the longitudinal axis **28** of the implant body **10** and a line **30** disposed tangent to the particular surface **16** in question. FIG. **4** illustrates an implant body having two tension surfaces (t_1 and t_2, respectively) and two compression surfaces (c_1 and c_2, respectively). The angle of incidence of tension surface t_1 is x_1, and the angle of incidence of tension surface t_2 is x_2. Similarly, the angle of incidence of compression surface c_1 is y_1 and the angle of incidence of compression surface c_2 is y_2.

Based upon these properties of tension surfaces **22** and compression surfaces **24**, the inventor has constructed an implant body **10** which substantially evenly distributes lateral stresses **5** placed upon the impact body **10** (such as illustrated in FIG. **3**). The inventor has accomplished this by providing an implant body **10** having alternating tension surfaces **22** and compression surfaces **24**. The surface areas and angles of incidence **26** of the tension surfaces **22** are chosen so that the portion of a lateral force **5** exerted by each of the tension surfaces increases from the centroid to the coronal end of the implant body. Conversely, the surface areas and angles of incidence of the compression surfaces **24** are chosen so that the portion of a lateral force **5** exerted by each of the compression surfaces **24** decreases from the centroid of the implant body to the coronal end of the implant body. Because the compression surfaces **24** exert more stress on adjacent bone **3** than do "straight surfaces," stress applied to bone **3** near the centroid **32** of the implant body of the invention **10** is greater than stress applied at the centroid **6** of prior art implant bodies **1**. Conversely, because tension surfaces **22** exert less stress on adjacent bone **3** than do "straight surfaces," the stress applied to bone **3** near the coronal end **18** of the implant body of the invention **10** is less than stress applied to bone **3** near the coronal end of a prior art implant body **1**. Thus, the stress diagram associated with the implant body of the invention more closely approximates FIG. **3** than FIG. **2**.

A typical embodiment of the implant body **10** of the present invention is illustrated in FIGS. **5–7**. The implant body **10** has a coronal end **18**, a distal end **20**, a longitudinal axis **28**, and a plurality of segments **34** proximate to the coronal end **18**.

Each segment **34** has a circular cross-section perpendicular to the longitudinal axis **28** and comprises a frustro-conical tension moiety **36** and a frustro-conical compression moiety **38**. Both moieties **36** and **38** have a maximum diameter **40**, a minimum diameter **42**, and a substantially flat surface area **16** disposed therebetween. Each such surface **16** is disposed at an angle of incidence **26** with respect to the longitudinal axis **28**. The maximum diameter **40** of the compression moiety **38** in each segment **34** is the same as the maximum diameter **40** of the tension moiety **36** in that segment **34**. As can be seen in FIG. **5**, each compression moiety **38** is joined to a tension moiety **36** along each moiety's respective maximum diameter **40**. As can also be seen in FIG. **5**, the minimum diameter **42** of each compression moiety **38** is identical to and is attached to the minimum diameter **42** of a tension moiety **36** of an adjacent segment **34**.

As noted above, the angles of incidence **26** and the surface areas of the compression moieties **38** are chosen so that, when the implant body **10** is implanted into bone **3** and a lateral force **5** is applied to the coronal end **18** of the implant body **10**, that portion of the lateral force **5** which is exerted by the compression moiety **38** of each segment **34** against the surrounding bone **3** is greater than that portion of the lateral force **5** which is exerted by the compression moiety **38** of an adjacent segment **34** disposed more proximate to the coronal end **18**. Also, the angles of incidence **26** and the surface areas of the tension moieties **36** are chosen so that, when the implant body **10** is implanted into bone **3** and a lateral force **5** is applied to the coronal end **18** of the implant body **10**, that portion of the lateral force **5** which is exerted by the tension moiety **36** of each segment **34** against the surrounding bone **3** is less than that portion of the lateral force **5** which is exerted by the tension moiety **36** of an adjacent segment **34** disposed more proximate to the coronal end **18**.

In one typical embodiment of the implant body **10** of the invention, the vertical width **44** of each individual segment **34** is generally held constant and the width of each compression moiety surface **16** is made greater than the width of the compression moiety surface **16** of an adjacent segment **34** disposed more proximate to the distal end **20**. In this embodiment, it is common, although not necessary, that the width of each tension moiety surface **16** is made greater than the width of the tension moiety surface **16** of an adjacent segment **34** disposed more proximate to the coronal end **18**.

In another typical embodiment of the implant body **10** of the invention, the vertical width of each segment **34** is held generally constant and the angle of incidence **26** of each compression moiety surface **16** is greater than the angle of incidence **26** of the compression moiety **38** of an adjacent segment **34** disposed more proximate to the distal end **20**. In this embodiment, it is common, although not necessary, that the angle of incidence **26** of each tension moiety surface **16** is greater than the angle of incidence **26** of the tension moiety surface **16** of an adjacent segment **34** disposed more proximate to the coronal end **18**.

One of ordinary skill in the art will immediately recognize that the typical embodiments described immediately above are not necessarily the only applications of the invention. Any combination of angles of incidence **26** and surface areas can be combined in a series of segments **34** so long as, when the implant body **10** is implanted into bone **3** and a lateral force **5** is applied to the coronal end **18** of the implant body **10**, (1) that portion of the lateral force **5** which is exerted by the compression moiety **38** of each segment **34** against the surrounding bone **3** is greater than the portion of the lateral force **5** which is exerted by the compression moiety **38** of an adjacent segment **34** disposed more proximate to the coronal end **18** and (2) that portion of the lateral force **5** which is exerted by the tension moiety **36** of each segment **34** against the surrounding bone **3** is less than that portion of the lateral force **5** which is exerted by the tension moiety **36** of an adjacent segment **34** disposed more proximate to the coronal end **18**.

The segments **34** can be discrete, as illustrated in the drawings. Alternatively, the segments **34** can be disposed in one continuous helix.

The implant body **10** is made from one of the many corrosion resistant metal alloys known in the art. For dental implants, the overall length of the implant body **10** is typically between about 8 millimeters and about 18 millimeters. FIG. **8** illustrated three different sizes of implant bodies **10**.

A typical dental implant body of the invention **10** has four segments **34**. The distance between the minimum diameter **42** of the compression segment **38** nearest the coronal end **18** of the implant body **10** and the minimum diameter **42** of the tension moiety **36** most distal to the coronal end **18** of the implant body **10** is typically between about 4 and about 8 millimeters. Implant bodies **10** having additional segments **34** are, of course, possible.

As can be seen from FIGS. **5** and **6**, the coronal end **18** of the implant body **10** defines a tapered coronal bore **44** having circular cross-sections perpendicular to the longitudinal axis **28** of the implant body **10**. The coronal bore **44** comprises a tapered distal section **46** and a coronal section **48**. The coronal section **48** has a substantially circular cross-section which is greater than the maximum cross-section of the distal section **46**. As will be seen below, the fact that the coronal section **48** has greater cross-section than the distal section **46** is important in that it allows for the attachment of a prosthesis attachment structure to be "countersunk" into the implant body **10**, below the level of the bone crest.

In a typical embodiment, the distal end **20** of the implant body **10** is slightly tapered towards the distal end **20**. Such tapering facilitates the firm installation of the implant body **10** into an implant site.

The distal end **20** of the implant body **10** can be externally threaded with self-tapping threads **50** as illustrated in FIG. **7**. In this embodiment, it is preferred that a pair of grooves **52**, disposed 180° apart, are defined within the exterior surface of the distal end **20**. The grooves **52** provide space for bone chips to gather when the implant body **10** is threaded into the implant site.

Preferably, the distal end **20** of the implant body **10** is knurled as illustrated in FIG. **8**. Most preferably, the distal end **20** of the implant body **10** is knurled and the knurling **54** has a cross-cut diamond shape, such as illustrated in FIG. **8**. Such knurling **54** creates its own bone chips at the time of insertion which further assist in redistributing stresses placed on the implant body **10**.

The implant body **10** is preferably used in conjunction with an anti-rotational plug **56** such as illustrated in FIGS. **9–12**. The plug **56** acts as a host for all coronal attachments. The plug **56** has a distal moiety **58**, a coronal moiety **60**, and a longitudinal axis **62**. The distal moiety **58** is sized and dimensioned to match the coronal bore **44** of the implant body **10** so that the plug **56** can be firmly affixed therein. The plug **56** may also be designed with parallel walls as shown in FIG. **9A** to assure parallelism between the longitudinal axis **26** of the implant body **10** and the longitudinal axis of the plug **56** during assembly. In this case, a Mores taper would preferably be defined in the attachment structure (described below). The coronal moiety **60** of the plug **56** would be machined most preferably at a 2° Mores taper to assure accuracy and stability.

The coronal moiety **60** has a maximum cross-section perpendicular to the longitudinal axis **62** of the plug **56** which is smaller than the maximum cross-section of the distal moiety **58** perpendicular to the longitudinal axis **62** of the plug **56**. As can be seen from FIG. **13** (which illustrates a typical plug **56** disposed within an implant **10**), the fact that the coronal moiety **60** of the plug **56** has a smaller cross-section than the distal moiety **58**, results in an annular gap **64** between the inner surface **66** of the coronal bore **44** within the implant body **10** and the coronal moiety **60** of the plug **56**. As will be shown below, this annular gap **64** facilitates the "countersinking" of the prosthesis attachment structure (described below) to the implant body-plug combination **76**. Alternatively, the tapered segment which creates the annular gap **64** may be defined in the prosthesis attachment structure in both the plug **56** and the prosthesis attachment structure to create an intimate fit upon proper seating.

The coronal moiety **60** of the plug **56** has at least one cross-section perpendicular to the longitudinal axis **62** of the plug which is non-circular. As will be seen below, this important feature allows for the reinstallation of an attachment structure (which has been previously removed from the coronal moiety **60** of the plug **56**) to precisely the original location. The non-circular cross-section of the coronal moiety **60** can take on any of a wide variety of shapes. As shown in FIG. **10**, the coronal moiety **60** of the plug **56** has a single cam projection **68**. In the embodiment illustrated in FIG. **12**, the coronal moiety **60** of the plug **56** has a hexagonal cross-section. Key-ways, locking splines, slots, flats and other cross-sectional shapes can also be used.

The coronal moiety **60** has an internally threaded plug bore **70** disposed along the longitudinal axis **62** of the plug **56**. This threaded plug bore **70** facilitates the installation of a prosthesis **12** or other attachments to the plug **56** by providing an attachment site for an attachment screw.

Regardless of the shape of the coronal moiety **60** of the plug **56**, it is preferred that the coronal moiety **60** be slightly tapered. It is most preferred that such tapering be a Mores taper **71** of between about 1° and about 2°, ideally, 1°, 30'. Such taper facilitates the installation of an attachment structure to the coronal moiety **60**.

In practice, the plug **56** is disposed within the implant body **10** as illustrated in FIGS. **13–14**. The plug **56** can be welded within the implant body **10**, cemented, or attached by any other suitable means.

The distal end **58** of the plug **56** is slightly typically tapered as is the distal section **46** of the coronal bore **44** within the implant body **10**. Such matched tapering facilitates the installation of the plug **56** within the implant body **10**. Alternatively, the plug **56** is not tapered. This shape may be preferred to assure proper orientation of the plug **56** prior to welding within the implant body **10**.

FIGS. 15–17 illustrate a typical healing cap 72 useful in the invention. The healing cap 72 can be used to seal the coronal end 74 of the tapered implant body-plug combination 76 after the combination 76 has been implanted into a patient (as illustrated in FIGS. 18 and 19). The healing cap 72 has a cap portion 78 sized and dimensioned to match up with the coronal end 18 of the implant body 10. The healing cap 72 also has a threaded distal end 80 sized and dimensioned to thread into the internally threaded plug bore 70 of the plug 56. The cap portion 78 has a coronal bore 82 with a non-circular cross-section. This bore 82 is adapted to accept a torquing tool which can be used to thread the healing cap 72 into the coronal moiety 60 of the plug 56.

FIGS. 20–21 illustrate a typical attachment structure 84 useful for attaching impression attachments, prostheses or other attachments to the implant body-plug combination 67. The attachment structure 84 comprises an elongated hollow section 86 having a coronal moiety 88 with an open coronal end 90, a distal moiety 92 with an open distal end 94 and a longitudinal axis 96. The distal end 94 of the attachment structure 84 is shaped and dimensioned to receive and engage the non-circular cross-section of the coronal moiety 60 of the plug 56. In the embodiment shown in the drawings, the distal end 94 of the attachment structure 84 is shaped to receive the coronal end 60 of a plug 56 having a cam projection 68, such as illustrated in FIG. 9. As mentioned above, this feature allows the practitioner to remove the attachment structure 84 from the plug 56 and thereafter reinstall the attachment structure 84 onto the plug 56 in precisely the same alignment in which it was initially installed. Alternatively, one or both components may also be machined parallel and alone be tapered to achieve the same results. The coronal moiety 88 is preferably detachable from the distal moiety 92.

The attachment structure 84 can be affixed to the plug 56 by an elongated first screw 98 which is disposed within the hollow section 86 of the attachment structure 84. Such a first screw 98 is illustrated in FIGS. 22 and 23. The threads of the first screw 98 are chosen to match the internal threads in the bore 70 of the plug 56. FIG. 24 illustrates the first screw 98 disposed within the attachment structure 84. The first screw 98 has a coronal bore 99 with a non-circular cross-section. This bore 99 is adapted to accept a torquing tool which can be used to thread the first screw 98 into the coronal moiety 60 of the plug 56.

In the embodiments illustrated in the drawings, the distal moiety 92 of the attachment structure 84 has a first external surface section 100 immediately proximate to the distal end 94 of the attachment structure 84 and a second external surface section 102 immediately proximate to the first external surface section 100. The cross-sections of the first and second external surface sections 100 and 102 are sized and dimensioned to match the cross-section of the external surface of the implant body 10 immediately proximate to the coronal end 18 of the implant body 10. The width 103 of the first external surface section 100 is substantially the same as the depth 104 of the coronal section 48 of the implant body coronal bore 44. As shown in FIG. 25, this design allows the first external surface section 100 to nest within the coronal section 18 of the coronal bore 44 of the implant body 10. The diameter of the second external surface section 102 is substantially the same as the diameter of the external surface of the implant body 10 immediately proximate to its coronal end 18. As illustrated in FIG. 25, this provides for a smooth transitional surface between the impact body 10 and the attachment structure 84.

FIGS. 25–27 illustrate the attachment structure 84 as it is combined with the implant body 10 and the plug 56, using the first screw 98.

FIG. 28 illustrates the combination illustrated in FIG. 25 in further combination with a dental prosthesis 12 attached to the attachment structure 84.

In many cases prior to the final installation of the prosthesis 12 onto the attachment structure 84, it is desirable to cover the attachment structure 84 with a sheath 106. Such a sheath 106 is illustrated in FIGS. 31–33. As shown in FIG. 31, to install the sheath 106, the practitioner first removes the coronal moiety 88 of the attachment structure 84. The sheath 106 can be made of a plastic material. Other suitable materials can, of course, be used, i.e., T_i, T_i 6-4 alloy or T_i 13—13, etc.

The sheath 106 has an open coronal end 108 and an open distal end 110. The coronal end 108 is sized and dimensioned to cover the coronal end 90 of the attachment structure 84. The opening 112 in the coronal end 108 of the sheath 106 is sized and dimensioned to receive a second screw 114 as illustrated in FIGS. 34 and 35. The second screw 114 is threaded in such a way that it can be attached within the bore 70 of the plug 56. The second screw 114 has a shoulder 116 sized and dimensioned to firmly retain the attachment structure 84 to the plug 56. The second screw 114 also has a head 118 sized and dimensioned to firmly attach the sheath 106 to the attachment structure 84. The second screw 114 has a coronal bore 119 with a non-circular cross-section. This bore 119 is adapted to accept a torquing tool which can be used to thread the second screw 114 into the coronal moiety 60 of the plug 56.

As illustrated in FIG. 36, the implant body-plug combination 76 can be conveniently packaged with an implant tool 120 within a protective cover 122 so that the practitioner can quickly and easily install the implant body-plug combination 76 by merely removing the cover 122 and using the installation tool 120 to install the implant body 10 within a pre-prepared implant site. A typical implant tool 120 is illustrated in FIGS. 37–44.

The tool 120 comprises a shank portion 124 which is attachable to a removable handle portion 126. The distal end 128 of the shank portion 124 is sized and dimensioned to match up and engage the coronal moiety 60 of the plug 56 and the coronal end 18 of the implant body 10. The distal end 128 of the shank 124 is sized and dimensioned to accept the removable handle portion 126. Both the handle portion 126 and the shank 124 are hollow so that a third screw 130 can be used to firmly attach the handle portion 126 to the shank 124 and the shank 124 to the plug 56 as illustrated in FIG. 36. The third screw 130 has a coronal bore 131 with a non-circular cross-section. This bore 131 is adapted to accept a torquing tool which can be used to thread the third screw 130 into the coronal moiety 60 of the plug 56.

In practice, the implant body of the invention 10 is installed into an implant site which has been previously prepared in the bone 3 of the patient. Such an implant site can be prepared using tapered drills such as those illustrated in FIGS. 45–50. The drill illustrated in FIG. 45 is a typical pilot drill 132. The drill illustrated in FIG. 48 is a larger drill 134 for use after a pilot hole is drilled (by the pilot 132 drill) to prepare the full dimension of the implant site.

Although the present invention has been described in considerable detail with reference to certain preferred versions, many other versions should be apparent to those skilled in the art. Therefore, the spirit and scope of the appending claims should not necessarily be limited to the description of the preferred versions contained herein.

What is claimed is:

1. An endosseous implant body for implantation into

bone, the body having a coronal end, a distal end, a longitudinal axis and a plurality of segments proximate to the coronal end, wherein:

(a) each segment has a circular cross-section perpendicular to the longitudinal axis and comprises a frustro-conical compression moiety and a frustro-conical tension moiety, both moieties have a maximum diameter, a minimum diameter and a substantially flat surface area disposed therebetween at an angle of incidence with respect to the longitudinal axis, the maximum diameter of the compression moiety being the same as the maximum diameter of the tension moiety and the compression moiety being joined to the tension moiety along each moiety's respective maximum diameter;

(b) the minimum diameter of each compression moiety is identical to and is attached to the minimum diameter of a tension moiety of an adjacent segment;

(c) the angles of incidence and the surface areas of the compression moieties are chosen so that, when the implant body is implanted into bone and a lateral force is applied to the coronal end of the implant body, that portion of the lateral force which is exerted by the compression moiety of each segment against the surrounding bone is greater than that portion of the lateral force which is exerted by the compression moiety of an adjacent segment disposed more proximate to the coronal end; and

(d) the angles of incidence and the surface areas of the tension moieties are chosen so that when the implant body is implanted into bone and a lateral force is applied to the coronal end of the implant body, that portion of the lateral force which is exerted by the tension moiety of each segment against the surrounding bone is less than that portion of the lateral force which is exerted by the tension moiety of an adjacent segment disposed more proximate to the coronal end.

2. The implant body of claim **1** having at least four segments and wherein the distance between the minimum diameter of the compression segment nearest the coronal end and the minimum diameter of the tension moiety most distal from the coronal end is between about 4 and about 8 millimeters.

3. The implant body of claim **1** wherein the distance between the coronal end and the distal end is between about 8 and about 18 millimeters.

4. The implant body of claim **1** wherein the width of each compression moiety surface between the minimum diameter of the compression moiety and the maximum diameter of the compression moiety is greater than the width of the compression moiety surface between the minimum diameter of the compression moiety and the maximum diameter of the compression moiety of an adjacent segment disposed more proximate to the distal end.

5. The implant body of claim **1** wherein the width of each tension moiety surface between the minimum diameter of the tension moiety and the maximum diameter of the tension moiety is greater than the width of the tension moiety surface between the minimum diameter of the tension moiety and the maximum diameter of the tension moiety of an adjacent segment disposed more proximate to the coronal end.

6. The implant body of claim **1** wherein the angle of incidence of each compression moiety surface between the minimum diameter of the compression moiety and the maximum diameter of the compression moiety is greater than the angle of incidence of the compression moiety surface between the minimum diameter of the compression moiety and the maximum diameter of the compression moiety of an adjacent segment disposed more proximate to the distal end.

7. The implant body of claim **1** wherein the angle of incidence of each tension moiety surface between the minimum diameter of the tension moiety and the maximum diameter of the tension moiety is greater than the angle of incidence of the tension moiety surface between the minimum diameter of the tension moiety and the maximum diameter of the tension moiety of the tension moiety of an adjacent segment disposed more proximate to the coronal end.

8. The implant body of claim **1** wherein the coronal end defines a tapered coronal bore having circular cross-sections perpendicular to the longitudinal axis, and wherein the coronal bore comprises a tapered distal section and a coronal section, the coronal section having a substantially circular cross-section which is greater than the maximum cross-section of the distal section.

9. The implant body of claim **1** wherein the exterior surface proximate to the distal end is externally threaded.

10. The implant body of claim **1** wherein the exterior surface proximate to the distal end is externally knurled.

11. An endosseous implant combination comprising:

(a) an implant body having a distal end, a coronal end and a longitudinal axis, the coronal end defining a tapered coronal bore having circular cross-sections perpendicular to the longitudinal axis; and

(b) a plug having a plug distal moiety, a plug coronal moiety and a longitudinal axis, the plug distal moiety being sized and dimensioned to match the coronal bore of the implant body and being affixed therein, the plug coronal moiety having a maximum cross-section perpendicular to the longitudinal axis which is smaller than the maximum cross-section of the plug distal moiety perpendicular to the longitudinal axis and less than a maximum cross-section of a portion of said coronal bore of said implant body for forming an annular gap therebetween for installation of an attachment structure therein, the plug coronal moiety having at least one cross-section perpendicular to the longitudinal axis which is non-circular and the plug coronal moiety defining an internally threaded plug bore disposed along the longitudinal axis of the plug.

12. The combination of claim **11** wherein the coronal moiety of the plug is tapered to a Mores taper of between about one degree and about two degrees.

13. The combination of claim **12** wherein the coronal moiety of the plug has at least one cross-section which is substantially hexagonal.

14. The combination of claim **11**, wherein the distal moiety of the plug is tapered.

15. The combination of claim **11** wherein the implant body coronal bore has a distal section and a coronal section, the distal section being tapered and having a maximum cross-sectional diameter which is less than the cross-sectional diameter of the coronal section and wherein the plug is disposed within the distal section of the implant body coronal bore.

16. The combination of claim **11** further comprising an attachment structure, the attachment structure comprising an elongated hollow section having a coronal moiety with an open coronal end, a distal moiety with an open distal end and a longitudinal axis, the distal end of the attachment structure being shaped and dimensioned to receive and engage the non-circular cross-section of the coronal moiety of the plug, the attachment structure being affixed to the plug by an

elongated screw disposed within the hollow section, the screw having a head and an externally threaded end, the threaded end being threaded into the plug bore, whereby the head of the screw is accessed for applying torque to the screw through the open proximal end of the attachment structure.

17. The combination of claim 16 wherein:

(a) the implant body coronal bore has a distal section and a coronal section, the distal section being tapered and having a maximum cross-sectional diameter which is less than the cross-sectional diameter of the coronal section;

(b) the distal moiety of the attachment structure has a first external surface section immediately proximate to the distal end of the attachment structure and a second external surface section immediately proximate to the first external surface section;

(c) the cross-sections of the first and second external surface sections are substantially circular as is the cross-section of the external surface of the implant body immediately proximate to the coronal end;

(d) the diameter of the first external surface section is substantially the same as the cross-sectional diameter of the coronal section of the implant body coronal bore and the diameter of the second external surface section is substantially the same as the external diameter of the external surface of the implant body immediately proximate to the coronal end; and

(e) the width of the first external surface section is substantially the same as the depth of the coronal section of the implant body coronal bore.

18. The combination of claim 16 further comprising a sheath for securely covering the open coronal end of the attachment structure, the sheath having a hollow body with an open distal end and an open proximal end, the open distal end being sized and dimensioned to conform to the proximal end of the attachment structure so that the sheath securely engages the coronal end of the attachment structure, the sheath being attached to the attachment structure by a screw engaged into the threaded plug bore, the screw having a head and an externally threaded end, the threaded end being threaded into the threaded plug bore and the head of the screw being accessed for applying torque to the screw through the open coronal end of the attachment structure.

19. The combination of claim 16 further comprising a dental prosthesis attached to the proximal end of the attachment structure.

20. The combination of claim 11 further comprising a healing cap having a threaded distal end and a coronal head, the threaded distal end being adapted to thread within the plug bore and the coronal head being sized and dimensioned to cover the coronal end of the implant body, the healing cap further comprising a coronal bore disposed coaxially with the longitudinal axis of the implant body and having a non-circular interior cross-section.

21. An endosseous implant delivery system combination comprising:

(a) an implant body having a distal end, a coronal end and a longitudinal axis, the coronal end defining a tapered coronal bore having circular cross-sections perpendicular to the longitudinal axis;

(b) a plug having a distal moiety, a coronal moiety and a longitudinal axis, the distal moiety being sized and dimensioned to match the coronal bore of the implant body and being affixed therein, the coronal moiety having a maximum cross-section perpendicular to the longitudinal axis which is smaller than the maximum cross-section of the distal moiety perpendicular to the longitudinal axis and less than a maximum cross-section of a portion of said coronal bore of said implant body for forming an annular gap therebetween, the coronal moiety having at least one cross-section perpendicular to the longitudinal axis which is non-circular and the coronal moiety defining a threaded plug bore disposed along the longitudinal axis of the plug; and

(c) an elongated hollow wrench having a hollow body, an open proximal end and an open distal end, the distal end being shaped for insert into said gap and dimensioned to receive and engage the non-circular cross-section of the coronal moiety of the plug, the wrench being attached to the plug by an elongated screw disposed within the hollow body of the wrench, the screw having a head and an externally threaded end, the threaded end being threaded into the plug bore, whereby the head of the screw is accessed for applying torque to the screw through the open proximal end of the wrench.

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